Exhibit "3"

UNITED STATES DISTRICT COURT

FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	Master File No. 2:12-MD-02327 MDL 2327
THIS DOCUMENT RELATES TO THE FOLLOWING CASES IN WAVE 1 OF MDL 200:	JOSEPH R. GOODWIN U.S. DISTRICT JUDGE
SHIRLEY FREEMAN, et al. v. ETHICON, INC., et al.	CIVIL ACTION FILE No. 2:12-CV-00490
SHIRLEY WALKER, et al. v. ETHICON, INC., et al.	CIVIL ACTION FILE No. 2:12-CV-00873
WILSON WOLFE, et al. v. ETHICON, INC., et al.	CIVIL ACTION FILE No. 2:12-CV-01286

Deposition of ROBERT BRIAN RAYBON, M.D., taken on behalf of the Defendants, pursuant to the stipulations agreed to herein, before Maxyne Bursky, Registered Professional Reporter, at 440 College Avenue, Athens, Georgia, on the 18th day of April, 2016, commencing at the hour of 8:51 a.m.

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ROBERT BRIAN RAYBON, M.D.,
having been first duly sworn, testifies as follows:
EXAMINATION
BY MR. KOOPMANN:

Q. Good morning.
A. Good morning.
Q. Please state your full name for the record, please.
A. Robert Brian Raybon.
Q. Good morning, Dr. Raybon. We met briefly off the record, but again for the record, my name is Barry Koopmann and I am one of the attorneys representing Johnson & Johnson/Ethicon in this litigation.

You understand we are here today to take your deposition regarding the Prolift device for the Wilson Wolfe case and the Prolift+M device for the Friedman and Walker cases?
A. Yes, sir.
Q. You have been deposed several times before; is that correct?
A. That's correct.
Q. So you are generally familiar with the process?

A. Yes, I am.
Q. I will give you just a couple reminders. If you don't understand one of my questions, please just ask me to repeat it or rephrase it and I will be happy to do so, but if you go ahead and answer my question, I will assume you understood it as I asked it. Is that fair?
A. Yes, sir.
Q. If you need to take a break at any time, please just let me know. I would just ask that if I have a question pending, that you answer the question before we take a break.
A. Yes, sir.
Q. Dr. Raybon, in giving your opinions regarding the Prolift and Prolift+M devices, it was important for you to be thorough and complete in your review of the available information regarding those products, is that fair?
A. That's a fair statement.
Q. Because whether you were thorough in doing your work in this case affects how worthy your opinions are of being believed, doesn't it?
A. I would say so.
(Deposition Exhibit 1 was marked for

identification.)
BY MR. KOOPMANN:
Q. I have marked as Deposition Exhibit Number 1 a copy of the notice for today's deposition.
MR. KOOPMANN: Did somebody just join on the phone?
MR. SHERIDAN: Yes, Tom Sheridan just joined from Simmons Hanly Conroy in connection with the Shirley Walker case.
MR. KOOPMANN: Thank you. We just got started about a minute ago, Mr. Sheridan.
MR. SHERIDAN: Thanks very much. I'm just going to mute my phone.
MR. KOOPMANN: Okay, thank you.
BY MR. KOOPMANN:
Q. Dr. Raybon, have you seen what I have marked as Deposition Exhibit 1 before this morning?
A. Yes, I have.
Q. Did you have a chance to take a look at the attached Exhibit A that includes some document requests that we made?
A. Yes, I have.
Q. Did you have a chance to go through those

document requests and try to comply with those and bring along whatever documents you had that were responsive to those requests?
A. Yes, sir.
Q. I see we have some file materials included over on the cabinet behind the court reporter. Is that the file materials that you brought along today?
A. That's correct.
Q. Number 1 on the list asked for all documents including but not limited to calculations, correspondence, data, calendar entries, notes and other materials relating to the compensation to be paid to you for your study and testimony in this case. Did you bring along some documents responsive to that request?
A. Yes, sir, I believe counsel has those over there including my invoices.
MR. HILL: Would it be easy for me just to identify to you what we brought, then you can go ahead and mark those?
MR. KOOPMANN: Yes, why don't we do that.
MR. HILL: Just for the record, we

have responded to the request of the notice and the attached exhibit and have brought with us or provided everything that we think is responsive to the various requests.
The first thing we have is a thumb drive with all of his reliance materials on the thumb drive.
MR. KOOPMANN: Why don't we mark that as Exhibit 2.
(Deposition Exhibit 2 was marked for identification.)
MR. HILL: The next thing we have is a set of notebooks as to each of the products, the Prolift+M and the Prolift which are tabbed documents evidencing each footnote in his report.
So you want to do the Prolift+M as the next exhibit number and the Prolift?
MR. KOOPMANN: Sure. So it is a two-volume --
MR. HILL: Two volumes on Prolift+M and three on the Prolift.
MR. KOOPMANN: I will mark the two

volumes of Prolift+M notebooks as Deposition Exhibit Number 3 and the three volumes of Prolift notebooks as Exhibit 4.

(Deposition Exhibits 3 and 4 were marked for identification.)

MR. HILL: Then we have just some emails from our firm to him showing various materials that were sent him.

MR. KOOPMANN: I will mark those as Deposition Exhibit Number 5.

(Deposition Exhibit 5 was marked for identification.)

MR. HILL: Then we have some invoices.

MR. KOOPMANN: Mark the invoices as Deposition Exhibit 6.

(Deposition Exhibit 6 was marked for identification.)

MR. HILL: Then we have his CV, this is an updated CV.

MR. KOOPMANN: I will mark the CV as Deposition Exhibit Number 7.

(Deposition Exhibit 7 was marked for

identification.)

MR. HILL: And you have got copies of his report. We just got his reports and the attachments on a disc, if you have any reason to mark that.

MR. KOOPMANN: I will mark the CD labeled Raybon Rule 26 Reports and Attachments as Deposition Exhibit Number 8.

(Deposition Exhibit 8 was marked for identification.)

MR. HILL: And we just got copies of his Exhibit B in each of his reports which are his reliance list. They go with the footnoted notebooks. I don't know if you want to mark those as, Exhibit B as a separate exhibit or not.

MR. KOOPMANN: I will mark Dr. Raybon's Prolift report that's being produced with his deposition materials and that we received previously. The Prolift report we'll mark as Deposition Exhibit 9, and the Prolift+M report as Exhibit 10.

(Deposition Exhibits 9 and 10 was marked for identification.)

MR. HILL: We have the Exhibit B to each report separately. I don't know if you wanted to mark those or not.

MR. KOOPMANN: Are these different documents?

MR. HILL: That's the Prolift report and that's the Prolift+M.

MR. KOOPMANN: I will mark the Prolift report reliance list as Exhibit 11.

(Deposition Exhibit 11 was marked for identification.)

MR. KOOPMANN: I will mark the Prolift+M report reliance list as Exhibit 12.

(Deposition Exhibit 12 was marked for identification.)

MR. HILL: And that's it.

BY MR. KOOPMANN:

Q. Dr. Raybon, were you following along with that?

A. Yes, sir.

Q. Have I now marked all of the file materials that you have brought along today?

A. Correct.

Q. That you have brought along today, I should say?

A. Yes, sir.

Q. One of the things that was requested on the deposition notice was copies of all medical records of the Plaintiffs in your possession. Do you have any of those?

A. No, I do not.

Q. You are just providing general product-related opinions in these cases?

A. That is correct, sir.

Q. One of the things on the deposition notice that we requested you bring along was copies of any deposition testimony relating to these cases. Would any deposition testimony that you have reviewed be included in those file materials?

A. It would.

Q. Did you review any deposition testimony in hard copy and mark it up?

A. No, I did not.

Q. Is it your practice to review deposition

testimony in electronic format when you did?
A. I prefer paper.
Q. So when you reviewed the paper, did you just not highlight or make notes on the transcripts?
A. No, I did not.
Q. One of the things that we requested were all documents including reports, summaries of data, studies or other documentation reflecting testing done by you relating to this case. Have you done any testing related to your opinions in this case?
A. No, I have not.
Q. You didn't do any physical examination of any of the Plaintiffs in these cases?
A. I did not.
Q. When I say these cases throughout this deposition, I mean the Freeman, Walker and Wilson Wolf cases. Okay?
A. Understood, sir.
Q. One of the things we asked for were any Ethicon products in your possession. Do you have any of those?
A. No, I do not.
Q. May I ask you a few questions about Defendant's Exhibit Number 6? These are the

invoices that you produced today; is that correct?
A. Yes, sir.
Q. Do these invoices represent all of the work that you have done regarding Ethicon pelvic mesh litigation?
A. That's correct.
Q. Is there work that you have done that is not yet included on one of these invoices?
A. There is an invoice that is in the process right now but I haven't submitted it yet.
Q. Do you know how much time in terms of hours you have worked that will be reflected on that invoice as of this point?
A. I really don't, no, sir.
Q. It looks like your invoices are current through March 31, 2016?
A. That is correct. I try to invoice if there is anything outlying on the first of each month.
Q. I am showing you what's been marked as Deposition Exhibit Number 5 which is the correspondence that you have produced today; is that correct?
A. Yes, sir.

Q. There are some emails here. There is an email from James Matthews to Tammy Tiller dated November 24, 2015 and the attachment was Document1.DOCX. Do you have any idea what that document was?
A. I do not.
Q. The subject was Document 2 pore size. Does that help you remember at all?
A. There was a lot of documentation I reviewed in this case and because of my close proximity, I'm literally located a mile and a half from here, most of the stuff was given to me in hard copy. Occasionally if something came in, they would email it to me and I would get a hard copy subsequent to follow because I prefer hard copies. So I feel confident that whatever is listed in that Document X is also in the materials over here to your right.
Q. I am handing you what's been marked as Deposition Exhibit Number 7. That's a copy of your CV; is that right?
A. Yes, sir.
Q. Is this CV up to date as of today?
A. Yes, it is.

Q. Is there anything that you included in your file materials in this case that you forgot to bring along today or is back in your office?
A. Not to my knowledge, no, sir.
Q. Did you discard anything from your file at any point?
A. No, sir.
Q. Are you prepared today to testify regarding your final opinions regarding the Prolift and Prolift+M devices that you will offer at the time of trial in these cases?
A. I am.
Q. Is there anything you have left to do?
A. No, sir, barring any new information that is presented to me.
Q. What did you do to prepare for today's deposition?
A. I reviewed my Rule 26 and the footnotes that were also in the report.
Q. Did you review your reports and the footnotes cited in your reports?
A. Correct.
Q. Did you go review all of the materials again that were set in those footnotes?

A. Some of them. I don't think I reviewed -- some of them are, how would you say, a lot fresher in my mind so I would not go back and review those, but if there was something else, then I would review the source.

Q. Were there particular documents that you have cited in your footnotes that you remember going back and reviewing in preparation for today's deposition?

A. No, sir, just that if I was shaky on one thing, I would go back and review it. I don't remember, there were several but I don't remember it being an exhaustive list.

Q. What else did you do to prepare for today's deposition?

A. That's pretty much it. I met with counsel yesterday for about two hours, maybe, tops, maybe a little less.

Q. That's Mr. Hill?

A. And Mr. Matthews.

Q. Anybody else there at that meeting?

A. No, sir.

Q. Did you have any meetings with Mr. Hill or Mr. Matthews prior to yesterday in preparation for

today's deposition?

A. No, I did not.

Q. Did you review any medical literature in preparation for today's deposition?

A. Not in preparation. I'm always constantly reading so I can't think of any in direct relation to this.

Q. You are constantly reading medical literature just to keep up with literature in your field?

A. Yes, sir.

Q. Is that something that you have done since you started your residency?

A. Yes, sir, pretty much. You kind of just need to have a steady review, I think, ongoing, to try to remain abreast of things. I think several years ago when the American Board of OB/GYN mandated we do a yearly recertification so there is always articles that they make us read in order to do that and I think that's been a wonderful addition and so that's helped me even to be more meticulous about it. There are times I'm better at it than others.

Q. Who originally retained you to work on the Ethicon pelvic mesh litigation?

A. This firm, Blasingame, Garrard.

Q. Is it Mr. Matthews that contacted you originally?

A. Mr. Matthews is the one I have had the most contact with and I do believe that he was the one that contacted me originally.

Q. Do you have any sort of retention agreement with the Blasingame firm?

A. I do not.

Q. How about any sort of confidentiality agreement?

A. Other than I just, any case I review like this, I don't discuss it. Is that what you are --

Q. Well, I mean, did you have to sign any sort of agreement saying that you wouldn't discuss the materials you review and learn about in connection with your work with the firm?

A. I believe, isn't there an order or something to that effect that we -- I don't know what you all call it when I was notified to be a part of this that I signed agreeing not to reveal or discuss any Ethicon-related documents, confidential documents and so forth. If that's what you are talking about, yes, I signed that.

Q. It sounds like you are referring to a protective order document?

A. I think so. I don't know the term.

Q. Do you recall signing anything that was prepared by somebody at the Blasingame law firm related to the confidentiality of the stuff that you are learning about?

A. I'm sorry, sir, I don't know the term. I feel like I have signed something that said, don't discuss it outside of the firm or with you.

Q. You don't know who prepared it, is that fair to say?

A. I think it -- I don't remember. I just, I remember, and I know enough now, obviously, even without signing something to not discuss it. But I signed something saying I will not discuss any of this material.

Q. What procedures were you trained on in your residency for the treatment of pelvic organ prolapse?

A. I was trained on what most would term a native tissue repair, anterior, posterior colporrhaphies, sacrospinous ligament fixations, paravaginal repairs and abdominal sacrocolpopexies.

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I don't remember -- also, and of course, you are talking about prolapse. There were other procedures, of course, for incontinence.

Q. What about uterosacral ligament fixations, were you trained on those?

A. That was a little bit more later. I did a couple years of fellowship and uterosacral ligament I think certainly was out there. It became a little more popular to me around when people started to do it laparoscopically. I don't remember doing one abdominally.

Q. So the sacrocolpopexies you were trained on in your residency were open procedures?

A. They were. When I came through initially, we did not nearly have the gadgetry that we have today in regards to laparoscopy so advanced laparoscopic techniques were really in their infancy. And so, no.

Q. So how about in your fellowship, what procedures in addition to those you just mentioned that you were trained on in your residency were you trained on in your fellowship?

A. You mean specifically in regard to pelvic organ prolapse?

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Q. Yes.

A. I oversee, I spent a great deal of time learning advanced laparoscopic approaches. These, at that time doing sacrocolpopexies, for example, laparoscopically was once again in its infancy because we are talking about the late 90s here and the fellow that I went to work with in France was known for being a laparoscopic pioneer.

So that was when I got my first exposure to that as well as laparoscopic paravaginal repairs. I do not remember if there were any laparoscopic uterosacral suspensions there, but that as far as the -- that was probably the biggest change, the vaginal stuff at that time was pretty much the same, even in France.

Q. When you were trained on anterior and posterior colporrhaphies and sacrospinous ligament fixations, paravaginal repairs and abdominal sacrocolpopexy in your residency, is it correct that there were no randomized controlled trials demonstrating the safety and efficacy of those procedures at that time?

A. I can't remember any randomized controlled trials. I know that, I guess it was more at that

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point I, in all honesty, you can knock me off my soap box here in a minute, but at that time I don't feel like issues in women's health in the 90s and earlier were given the attention it deserved and I think probably late 90s, early 2000s you started to see more vigorous research being performed whether it was in regards to surgery or medications used to treat females for anything, in other words, the research was all based on white males there.

And so I think at that time, that's 20-something years ago, I do not remember there being any randomized controlled trials.

Q. So at the time you were in your residency or even completed your residency, you don't remember there being randomized controlled trials on the procedures you were trained on to treat pelvic organ prolapse?

A. I do not remember. I think most of them were reviews or case series or that type of thing.

Q. Before you do any sort of surgery on a patient, do you try to learn all about the risks associated with that procedure?

A. I do.

Q. Do you think you owe it to your patients

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to try to do that?

A. I do.

Q. Would it be a fair statement to say that in the 1960s and 70s and 80s, surgeons in your field did not wait for RCTs to be done in order to adopt and try a surgical procedure with or without mesh to treat pelvic organ prolapse?

A. Not having been alive back then, but from my historical perspective, I think things were probably done more along the lines of, hey, I've got a good idea, let's try this and see how it goes. So then it should be a question of, I don't think as much emphasis was placed on randomized controlled trials at that time as it is today.

Q. Is it fair to say based on your understanding of how medicine was practiced back then that surgeons at that time practiced what was the standard of care at the time based on the technology that was available?

A. I think that's a fair statement, yes, sir.

Q. Sacrocolpopexy uses mesh, correct?

A. It does. It is probably, in the field of urogynecology or female pelvic medicine, it's probably, I'm confident it is the longest running

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procedure utilizing mesh. When it first came out, it used more fascia that was harvested from one of a couple places in the body, but I believe it was in the 80s, I believe, perhaps, mid-80s, late 80s where mesh was begun to be used.

Q. Do you perform sacrocolpopexies today?

A. I do.

Q. Are they open procedures or laparoscopic?

A. 99.9 percent of mine are laparoscopic.

Q. Was that a gradual transition that you made from doing the abdominal open sacrocolpopexies to the laparoscopic abdominal sacrocolpopexies?

A. I would say so. My time in France really, it opened my eyes as far as what could be accomplished laparoscopically and then when I came back to the states over the next several years, there was more and more interest in what could be performed laparoscopically in all procedures. And so as that became known -- and then there was some studies that came out that kind of revealed that a laparoscopic approach in the right hands was just as effective as an abdominal approach.

It really got my interest up and then at that point I sought out people to work with and so

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forth to further -- I feel I had the basic laparoscopic skills necessary but I think it is important to continue to try to learn and I did that continually up until a few years ago.

Q. For how long has it been the case that 99 percent of the sacrocolpopexies you have performed have been laparoscopic?

A. Definitely five years, I would say. It may be earlier, but I feel very confident it is five years if not more.

Q. How many abdominal sacrocolpopexies would you say you perform in an average year?

A. One, if that, and that's usually -- I had one lady last year that just did not want mesh at all and I felt like the biologic grafts that were available, she did not want that either. So we did an abdominal one and harvested fascia as we went in.

Q. Rectus fascia?

A. Rectus fascia, that's correct.

Q. When you do perform an abdominal sacrocolpopexy, do you sometimes use mesh?

A. Yes, sir.

Q. What mesh do you use?

A. In the last few years I'd say the

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predominant one has been the Coloplast Restorelle, R-E-S-T-O-R-E-L-L-E. I have also used some of the Caldera, C-A-L-D-E-R-A, mesh. I think that's pretty much it.

Q. Do you know what the pore size is of the Coloplast Restorelle mesh you use in sacrocolpopexies?

A. Yes, sir, it is right around -- oh, wait a minute, I'm thinking about the weight. The weight is very low. It's a macroporous mesh. I don't remember, the pore size is quite large. I'm sorry, I'm getting it confused with the weight of the mesh.

Q. I was going to ask about that next, do you remember what the weight is of the Restorelle mesh?

A. Around 20 micrograms, I believe, it is either 19 or 20. I believe they, in this country, if I am not mistaken, they have a lock on the market in being able to say that they have the lowest weight of the mesh out. There is one that's lower but it's only available overseas in Europe.

Q. What is the Restorelle mesh made of?

A. Polypropylene.

Q. Have you reviewed the material safety data sheet for the Coloplast Restorelle meshes of

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polypropylene?

A. I have. And I also spoke with their research people and the president of the company or that division, whatever, vice president, president with that with some of the other litigation that came out that raised my concerns of that. And I went back and I looked at that.

Q. How did you obtain the MSDS for the Restorelle mesh's polypropylene?

A. I think it was from some of their R&D people, Because at the time -- this company no longer exists. But AMS/Astora, Astora just went out of business. But I did the same with them there because there were some concerns with some of the manufacturers about raw material.

Q. Did you make any effort to determine whether the polypropylene in the Coloplast Restorelle mesh degrades?

A. That, I don't remember. I remember my big concern was this was the raw material and the product is suitable for human implantation. Some of the other manufacturers, the raw material specifically stated, this should not be used in humans permanently and that was my biggest concern

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at that time.
Q. Did the raw material for the polypropylene used in the Prolift and Prolift+M meshes, did those MSDSs say anything about the polypropylene being unsuitable for use in humans?
A. I don't know that I have seen the MSDSs on polypropylene that is in Prolift.
Q. Did you ask Coloplast or view any internal company documents before you started using the Coloplast Restorelle product?
A. No, sir. I asked for the information, I told you, and I had a face-to-face conversation with either the vice president in the US or the president specifically asking them that question, which in lieu of getting such documents, I thought that was best to just go to the top. At the time, some of the, I made the request of some other manufacturers too and I never heard back from them.
Q. Did you make any effort to determine whether the mesh in the Coloplast Restorelle is cytotoxic?
A. You mean, did I do any laboratory bench testing or anything?
Q. Any sort of investigation whatsoever?

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A. Not specifically that, no.
Q. Is there more published data on Coloplast Restorelle than there is on Gynemesh PS?
A. That's a good question, I would say there is probably a little more data out there on Gynemesh PS, my guess would be, but I don't, that's a guess. That's an educated guess, I would say.
Q. What's the Caldera mesh that you use in your sacrocolpopexies from time to time?
A. It's also polypropylene.
Q. Do you remember what the name of the mesh is?
A. I'm sorry, sir, I do not. That's on the tip of my tongue. It was, we have just started using some of it at the hospital here and I don't, I'm sorry, it escapes me.
Q. Do you have any colleagues at the hospital in Athens that you work at that use Gynemesh PS in pelvic organ prolapse repairs?
A. No, sir.
Q. Have you asked them all?
A. I'm pretty much the only one that does it. There are a few here and there that will do some abdominal sacrocolpopexies. There's a couple at the

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other hospital in town that do robotics and as far as volume goes, I'm certainly the highest. I think a lot of the other ones have followed kind of, I think what has happened is they have called to see what I am using and then use what I'm using. One has outright asked me, but I kind of get the impression that's what's happened with some of the others but I don't know that to be absolute.
Q. How many gynecologists are there at the hospital here in town that you work at?
A. I don't know the exact number but I think it's probably between 30 and 40.
Q. Do they all perform surgeries?
A. Most of them do. Quite a number of them are heavier with obstetrics. I say most of them do some surgery but I would say there's only a couple that do what I would say are the more advanced laparoscopic procedures.
Q. Do any of your colleagues -- first of all, what's the hospital called?
A. Athens Regional Medical Center. There's another hospital in town that I do not have privileges at.
Q. Have you sought privileges there?

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A. I have not.
Q. Do any of your OB/GYN surgeon colleagues at Athens Regional Medical Center use any of the Ethicon incontinence slings?
A. I do not know that for sure but I think that TVT, the name brand TVT, we use TVT now to refer to kind of the retropubic approach in general but the actual name brand Gynecare TVT, I think there are a couple.
Q. Have you ever had any conversations with those surgeon colleagues about their use of the Ethicon name brand TVT slings?
A. I have not.
Q. Did it raise any concerns to these colleagues about their use of the Ethicon TVT slings?
A. I don't believe there has been any concerns from them for the incontinence procedures, no, sir.
Q. You didn't report any concerns that you had to them about their use of the TVT slings?
A. No, I did not.
Q. What's the pore size of the Caldera mesh that you use in some of your sacrocolpopexies?

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A. It is a macroporous mesh as well. I cannot remember the exact one.
Q. Do you remember what the weight is of the Caldera mesh?
A. It's, I believe, and if I'm not mistaken, it is down in the 20s as well. I just looked at that the other day, as a matter of fact. But it is definitely not lower than Restorelle.
Q. What's your definition of macroporous for meshes?
A. Well, I think when you look at the different types of mesh according to Emmett's classification, I guess technically anything above 75 microns is going to be considered macroporous. However, in practice, most of the manufacturers out there, it's much, much larger than that ranging from, I have seen it range from 500 to 1,500 there. And so I'd say technically speaking, anything above that.
Q. Above the 75?
A. Yes, sir.
Q. So anything above 75 microns is macroporous in your opinion?
A. According to Emmett's classification, yes,

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sir.
Q. How many open abdominal sacrocolpopexies would you say you have performed in your career?
A. It's been several hundred. I would say in the last few years, it's as I said, it's only been one, maybe there's been a year I have done two. In the last five or more years, it's 2016, I might even go back ten years. A while ago you asked about the laparoscopic and I said five years. It might be closer to ten years on the laparoscopic. But it's been quite a number.
Q. So you perform hundreds of open abdominal sacrocolpopexies in your career?
A. Yes, sir. I have been in practice, even at my current, for 18 years. So I roughly do, just in the last few years, I roughly do 50 to 60 laparoscopic sacrocolpopexies a year and so even if you go down on that 10 or 20, that's going to still rack up to several hundred there. Obviously, I have kept a little closer track over the last few years than I did 15 years ago, I couldn't give you the absolute number.
Q. Do you keep any sort of case log?
A. No, sir.

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Q. I want to make sure I didn't misunderstand something you said earlier. I think you just told me that you have done about 50 to 60 laparoscopic sacrocolpopexies over the last few years; is that correct?
A. Yes, sir, definitely the last five years, I can attest to that number. It probably, it may be up to 10, but I can definitely say that for the last five years. And the reason I know that is we have really worked on getting a team together and getting our times down and that's why I know that.
Q. Did you also tell me that within the past year, you have done maybe one sacrocolpopexy?
A. Abdominal sacrocolpopexy. I'm sorry. I was not clear.
Q. That's all right. One open abdominal --
A. Abdominal sacrocolpopexy, my apologies, yes.
Q. In an open abdominal sacrocolpopexy, is a long incision made into the abdomen?
A. It is and it can be longer based on whether or not a hysterectomy needs to be performed concurrently or so forth. You can sometimes sneak in with a slightly smaller incision. Most of the

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time, I would do what's called a transverse incision where the incision is made from the left to the right side. It's also done through an up and down incision. People will refer to it from the pubic symphysis towards the umbilicus.
Q. How long is the incision in an abdominal sacrocolpopexy if you are not performing a concomitant hysterectomy?
A. It's going to be 12 to 15 centimeters, probably eight to ten inches. Once again, it will depend on the patient, the anatomy, the obesity, prior surgeries, that sort of thing.
Q. How long, how much longer would that incision be in an average case if a concomitant hysterectomy is being performed?
A. Well, an average case, I am going to make the assumption that the uterus is not enlarged, it is kind of a normal sized uterus. And a lot of these patients, they would be, they are going to be menopausal which is going to contribute to the smaller size.
So probably in those cases, it will be about the same. If you have a younger woman, let's say that has fibroids or an enlarged uterus, then it

could probably go up by another three to four inches or five to ten centimeters, something like that.

Q. Is vaginal mesh exposure possible with an abdominal sacrocolpopexy?

A. Yes, it is.

Q. Is vaginal mesh exposure possible with a laparoscopic colpopexy?

A. Yes, sir. You were talking open abdominal a minute ago?

Q. Yes.

A. Okay, I'm sorry, I just wanted to make sure I was clear.

Q. But vaginal mesh exposure is possible with both an open abdominal sacrocolpopexy and a laparoscopic colpopexy, correct?

A. That is correct.

Q. Mesh exposure is a well-known risk of any surgery involving mesh; is that correct?

A. We are talking in pelvic prolapse procedures, I assume we are limiting our --

Q. Yes. Let me reask the question.

Mesh exposure is a well-known risk of any pelvic organ prolapse surgery involving mesh, correct?

A. Correct.

Q. The abdominal sacrocolpopexy procedure has been performed since the 60s, correct?

A. That is correct. That's my understanding. With the mesh it's been since the 80s, I think, I might be wrong, but I think it's been since the 80s.

Q. When did you learn to use CR Bard's Avaulta product?

A. Roughly around 2005-ish, plus/minus. I'm sorry, I don't remember the exact date.

Q. When did you first learn to use the Prolift?

A. It is probably not too long after that. I learned, I had experience with the Avaulta first and then at that time, for lack of a better term, what I would term the mesh wars were heating up and it was probably within six months I had exposure to Prolift there.

Q. When you say mesh wars, you mean mesh wars in terms of companies competing to get doctors to use their product?

A. Yes, sir.

Q. Where did you first learn to use the Ethicon Prolift device?

A. That's a very interesting question there. Actually, I got involved with CR Bard towards the end of the development of Avaulta. It was not yet out.

So I did attend a couple of cadaver courses where they were, for lack of a better term, were putting the finishing touches on what they considered the final product was going to be there. So that was when I got involved.

The reason I'm saying this is I attended a very large cadaver course that CR Bard put on in Tennessee, it was in Memphis and there is a training facility there that I think technically belongs to orthopedists but it is quite a nice training facility. And they put on one of the biggest cadaver courses -- excuse me, it wasn't really a course. People weren't -- I guess it was and it wasn't.

The people they brought in like myself had a tremendous amount of experience in pelvic floor. These were not people we were training off the street, if you will. They were quite, these people that I remember all had a lot of experience.

I have never seen another cadaver course

like this, but we must have had ten cadavers or more. And over in this section of the room was the Avaulta, over in this section of the room was Apogee and Perigee, and over in this section of the room was Prolift there.

They had preceptors there that actually taught Apogee and Perigee and Prolift that were some of the very early users of those devices. So it was a very long cadaver course there.

There was a little bit of what I would call the didactic there but not as much as it was just hands-on there. So basically, I was taught the Prolift at that, at a CR Bard course by one of the Ethicon preceptors.

I know that makes -- that's crazy. I have never heard of another situation like that. But that was my first exposure to it.

Q. How do you know it was an Ethicon preceptor that taught how to use the Prolift at that cadaver lab?

A. Because that's what he said.

Q. Do you remember who that was?

A. I do not. Sorry, it's been like twelve years ago.

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Q. Do you remember anything about him? Did he have an accent or anything like that?
A. I don't remember, no, sir.
Q. Do you remember what he looked like?
A. I remember it was a man.
Q. How many surgeons were at this event, roughly?
A. It was quite, I want to say it was about 30. I mean, these people were kind of hand-picked to be there and they were, once again, remember CR Bard put it on and the people that were picked to be there, it may not have even been 30, it may have been like 20 actually because it was not the reps, the sales force that was picking these people. I think it was more the R&D people.
And while we could learn the other ones, they also wanted us to, obviously, rotate amongst the stations, if you will. And one of their things was that they wanted feedback on ease of use of the product, that sort of thing, did we have an opinion, that sort of thing.
Q. Did this cadaver lab seem more marketing in nature or educational in nature or was it just a mix?

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A. I think it was a mix there. My first guess was it was more, obviously, I think there was an effort to do some marketing because here were people that, attending that probably in their respective geographical areas are going to be thought leaders or KOLs there.
And so, obviously, I think there was an undercurrent of that, but I also feel like they really wanted to know, if I remember right, I think Bard was kind of the, if I remember right, AMS and Ethicon had already made it to the market there and Bard was trying to catch up.
Q. Do you remember any of the other attendees there, the names?
A. I do not. One thing I, person I do remember because I ended up working with him over the next several years was Jim Ross. He was one of the, some people would say, the father of Avaulta, if you will. I do remember he was there because that was my first exposure to him.
Q. Is this an event that Bard paid for you to travel to?
A. They did. They covered lodging and expenses but nobody was paid an honorarium, not the

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attendees. I'm sure the other people were that were teaching.
Q. But Bard covered your flight and your hotel?
A. Yes, sir.
Q. Maybe some meals?
A. Meals, yes, sir.
Q. After that cadaver course, did you ever use the Apogee or Perigee products?
A. I did not. And the reason for that is, as you probably know now or have come across in this litigation, a lot of hospitals are on different contracts there. And so there are certain contracts that you can get this brand or this brand but not this brand. And so more and more hospitals in the last decade have had to choose. And sometimes it's not easy to ameliorate or placate your surgeons because everyone wants their own thing.
But that is why I did not. I never had any experience with the Apogee and Perigee, the AMS products. I learned how to do it but then it was not some, it was going to be very cost prohibitive at our hospital to get it so I never tried it.
Q. Did you ever make a request at your

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hospital to have them stock the Apogee or Perigee products?
A. I do not remember. I probably did but I didn't have the juice at the hospital I have now, if that makes sense.
Q. Did you have to make a request to your hospital to have them stock the Prolift devices or were they already being stocked?
A. They were not already being stocked. The hospital there at that time, Stevens County Hospital in Toccoa, that's the other hospital I'm at, and I was the only one doing the majority, I should say of this sort of thing. And, no, they were not stocking it at that time.
Q. Were the Avaulta, Apogee and Perigee devices that you also learned about at that cadaver lab, polypropylene devices?
A. Yes, sir, the Avaulta also was, the initial Avaulta at that time, the biosynthetic, it also had a collagen coating on it.
Q. So it had a polypropylene component with a different coating on it?
A. Correct, and once it got in the body, you could see the coating almost become slimy, if you

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will. You definitely had a coating and I remember the demonstration ones that I had if they were left out in the ambient temperature, they would get "cracky," cracked there. I don't believe any of the other manufacturers at that time had a coating.

I think AMS had a biologic that could also be used with the Apogee and Perigee needles, but...

Q. Did Avaulta, Apogee and Perigee products all involve the implantation of the mesh via trocars and cannulas?

A. Yes, sir, all of the, unless you were going to do a, what I call a free, hands-on repair with a graft, biologic or synthetic, all of them at that time utilized trocars there, all the, quote, kits. I mean, you could certainly deal with a suture carrier like a Capio device or Deschamps, or something like that, old-time ligature carrier and hand-sew in your own, which people did, which I had done a lot of out there. But of the kits at that time, all of them were transobturator and transgluteal there.

Q. Did you ever attend any Prolift training that was put on by Ethicon?

A. No, I did not.

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Q. Did you ever attend any Prolift+M training?

A. No, I did not.

Q. Did you have an opportunity to ask questions at this cadaver lab in Memphis?

A. I did.

Q. Did you get to perform the procedure on the cadaver?

A. I did. I did all of the procedures several times.

Q. So Bard paid for you to go to Memphis and attend this cadaver lab and you left that cadaver lab and started using some Prolift devices?

A. I did. I had already received the information from the rep at that time. I remember very clearly him coming by the office. I think it was more like a cold call, oh, well, you know, hey, I've got this new device. I'm sure it's not something really you are interested in, kind of, sort of. I think they had to have so many cold calls listed.

And I kind of remember laughing and taking my laptop and flipping it around and go, you mean a repair like this?

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And at that time I was using a tremendous amount of biologics and we were doing some quite big prolapses vaginally and I think it kind of caught him off guard. And he was like, holy smoke, this person maybe does know what he is talking about.

So at that point I remember getting some product information from him and some of the DVDs or CDs that were out at that time which I had already reviewed.

But even then I was not, I wasn't going to do it until I had some training. At that particular time when I met him, I didn't know -- well, I knew this cadaver lab I think was getting ready to happen. I didn't know all of this other stuff was going to be there. I thought it was just going to be Avaulta. I was kind of surprised that the other two main players were there as well.

Q. Did you ever do freehand cutting of Gynemesh PS in your prolapse repairs?

A. Not Gynemesh PS, no, sir.

Q. But before using the Prolift or the Avaulta or any other pelvic organ prolapse transvaginal mesh kits with precut pieces of mesh, you did use just freehand cutting of mesh for

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prolapse repairs?

A. I did, and I had a tremendous amount of experience at that time with Pelvitex. It was a Bard/Sofradim product, S-O-F-R-A-D-I-M, Sofradim product and it was the collagen coated mesh so it was the same mesh that was used in the initial Avaulta biosynthetic. And so I had done a tremendous amount of that. I had done a tremendous amount of, at the time, Pelvicol and subsequent PelviSoft and so all of our stuff we were doing then for years when we used grafts had been hand-sewn, free-cut, hand-sewn, no kits.

Q. How would you cut the mesh when you used it in that way?

A. I tried two different ways. There were certainly people that were talking about, hey, this cutout, if you will, will work for the majority of the people and there were things published or communications between docs where, hey, this dimension and all works for me 99 percent of the time and I tried some of that but I also would cut it individually to suit the patient there. And that is the way that I ended up preferring to do it, is not use a one-size-fits-all cutout.

And I would tailor it to each individual patient so that -- because at that time I took my mesh repairs and biological graft repairs, what is termed sidewall to sidewall, it went all the way out laterally and was not just in the middle over the big part of the prolapse.

Q. Do you no longer do that, do sidewall to sidewall repairs?

A. I do a lot more, we have kind of come full circle. As I guess I'm sure you have gotten the inkling from the litigation, we are doing a lot more suture repairs, site-specific repairs these days, native tissue repairs to cover all of that.

Compared to the time frame in question, 2005-2006, there was this kind of push to, wait a minute, let's look at these mesh kits, let's do this, let's do that. And so we are doing a lot of those and I do do in people that have had failures, I have done, I still do the hand-sewn free stuff. I do probably a few more biologics like cadaveric skin grafts, in those instances.

I used to do a bit more of the mesh, but the problem has been with the litigation and the TV ads and so forth and the stuff on the internet,

people have been very leery of mesh put in through the vagina there.

And so -- anyway, I'm sorry if I'm being long-winded.

Q. That's okay. Nowadays, if you decide to do a transvaginal mesh repair in a patient, in what sort of situation would you decide to do that?

A. These are roughly my parameters there. 50 and less, years of age and less, I don't even want to discuss it. I should say there's always a caveat in there, wherever, but there's always a potential special case. But in general, 50 and less, I don't want to discuss it.

70 and above, depending on the situation there, I kind of look at the merits of, would a vaginal approach be beneficial in this patient. So, for example, last week -- actually I didn't do a vaginal mesh case on her, but I opted to do this case vaginally whereas what the lady really needed was a sacrocolpopexy but because of medical issues, she had severe lung issues, cardiac issues, her consultant physicians did not want her to have general anesthesia so that limited me to regional anesthesia and given her COPD, I didn't want to put

a big cup on her tummy, which has the effect of making people not want to breathe deep because it hurts. So I did her case vaginally.

So similarly over the course of the last several years, I have had cases here and there where people had significant prolapse and utilizing vaginal mesh allowed me to get in and out very rapidly. I have even had a couple of cases in women in their 80s that, just because of technical reasons, a colpocleisis would not be easily performed there.

So, for example, if someone had a tremendous amount of anterior prolapse but the posterior aspect of the prolapse, the vaginal vault had not totally everted, then it can technically be somewhat difficult to do a colpectomy or a colpocleisis. But I have had cases where I have been able to go in and out very rapidly with that.

Now, the last one is what do you do in the 50 to 70 range. Those cases I really do take on a case-by-case basis.

If I look at a 60-year-old patient and when she walks in I think, my first thought is, man, she's probably about 85 years old, then I

immediately, then when I say, I go, wait a minute, what is the morbidity here, what is the medical issues this patient is facing.

Flip side, if I have a 60-year-old patient and she's in great health, acting more like she's in the lower 50s, if you will, then, especially with significant apical prolapse, I'm going to offer her sacrocolpopexy. The other caveat to this is sexual activity there.

I really, I'm strong -- I'm tending to shy away from mesh use in the vagina in women that are still very sexually active there. So that also factors in.

Once again, I'm sorry, I know that's a long-winded answer, but those are basically where I start from.

Q. Are you also steering clear of mesh repairs, of sacrocolpopexy mesh repairs?

A. In 50-year-olds or 40-year-olds?

Q. In sexually active women?

A. No, I do, I do those quite readily, actually.

Q. So is it fair to say that there are some of your patients for whom you decide a transvaginal

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mesh repair for their prolapse is the most appropriate course of treatment?
A. There are and I would say compared to 2005-ish, '6-ish, the numbers have, I'm super more selective than we were back then. Back then in '05, '06, I think there was this, we have nirvana here, this is going to take, take away the need to do a bigger sacrocolpopexy, this is going to take away that. I think now we realize there was too much of a rush in that direction.
Q. At the cadaver lab back in 2005, were complications discussed?
A. I do not remember. Sorry.
Q. Do you recall asking if pain was a potential risk of the Prolift procedure?
A. At this course?
Q. Yes.
A. I do not remember if I asked that or not.
Q. Do you recall asking if dyspareunia was a potential risk of the Prolift procedure at this cadaver lab?
A. I don't remember at this cadaver lab, no, if I asked that.
Q. When was the first time you read the

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Prolift instructions for use or IFU?
A. That would have been when that, as I said, that rep came around back in that time. As I said, I'm pretty confident he came by before I went to this cadaver lab and so I think he gave me an IFU or some other product information as well as a DVD or CD to review.
Q. Do you remember who that rep was?
A. Yes, his name was Marquel, M-A-R-Q-U-E-L, Fleetwood, just like the Cadillac.
Q. Do you think that was also the first time you read a Prolift brochure, when Mr. Fleetwood gave you some product information?
A. I'm pretty confident that was. Remember at that time, this stuff was just getting going, I mean, literally, I can't swear to this, but I don't think Prolift had been out on the market in Georgia, or nationally, for that matter, that long. I think it, put it to you this way: He told me years later that, I think I did the first Prolift in Georgia there.
Q. So is it fair for me to understand that the first time you ever heard of the Prolift device was when Mr. Fleetwood mentioned it to you and then

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you learned how to implant it at the cadaver lab?
A. Yes, sir, and I had reviewed the materials he had given me as well.
Q. I think you indicated in your Rule 26 report that you used a Prolift device about 25 times; is that correct?
A. Correct.
Q. Was it 25 times exactly or about there?
A. I tried to go on the low end. I feel it was probably higher than that but I want to -- I definitely feel confident with 25.
Q. Over what time span did you use those 25 Prolift devices?
A. At that time, I was doing about, it ranged from 100 to about 100 -- I remember my high point there was 130 vaginal repairs there in a year. And so I'm pretty confident it was over the course of the next six months, whenever I started that.
And maybe even less, because I was, I mean, very, very, very busy during that time and I was, I would kind of, you know, I was doing Avaulta at the same time. And because at that time, my thinking was, certainly maybe Avaulta, maybe Bard doesn't have a lock on the best way to do this. I

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mean, I should at least explore something else and I did get trained on it and had reviewed everything. So that's why I chose Prolift.
If I hadn't been, I probably, it would have been a toss-up at that point that I did Apogee or Perigee or Prolift and I probably at that point would have had to go to training to do one of those two.
Q. So after you left the cadaver lab, was it the case that the Avaulta was not on the market so you couldn't go back and start using that again?
A. It was just getting ready to get released, like literally within a month or two of that lab because I did the first one of those in the world when it came out commercially.
Obviously, I did not, Jim Ross did the, a lot of the initial work, but before it was commercially available, that's what they would say, when I would teach at these conferences or whatever, they would say, Raybon did the first commercially available Avaulta in the world. So it was pretty soon after that.
Q. Were there aspects of the Prolift device or the procedure to implant the Prolift device that

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you found useful based on your learning about the Apogee/Perigee, the Avaulta and Prolift in that cadaver lab?

A. I remember, at the time I remember thinking that the Avaulta was a little easier to use. The one thing I did think that Prolift was perhaps -- at the time I thought, well, it's got these little cannulas that leave it through so you are not pulling the arms through the tissue, like sawing it there.

I thought, is that an advantage or not. At the time people didn't really know.

But I was pretty comfortable and remained comfortable. And one of the big keys with both of those or any of them is the proper dissection of their, and knowledge of the anatomy, this is critical and that is something that I feel like I had down. The dissection was practically, if you wanted a nice, thick, dissection which is something I had already been doing with the hand-sewn meshes and I was already going out very laterally and so forth to do these. So the dissection was one of the hardest things to get across to people.

I remember going to these courses and say,

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okay, go ahead and create this space, you are the first one on the cadaver, and have people look at me and go, what space are you talking about?

And I would just, I would go, oh, my.

Anyway, but that was the one good thing, is that if you had a dissection down, that was a huge part of it. And then, of course, the other part I think that was difficult for some people to get a hold of, was the, conceptually in the three-dimensional pelvis, appreciating where your trocars are when you are passing them blindly through this space, whether it is Prolift, Avaulta or Apogee/Perigee. I think some people had a hard time conceptualizing that.

Q. Was it the case that the Apogee and the Perigee and the Avaulta also involved blind passage of trocars?

A. All of the three kits around at that time, Apogee/Perigee, Avaulta and Prolift, those were the three big players, those were the three initial kits on the market and they all involved blind passes.

Q. So you found the cannulas that were used with the Prolift device to be helpful because they enabled you to pass the arms and implant the device

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without passing the arms directly through tissue; is that correct?

A. At that time I thought that that might be a potential advantage.

Q. Did you participate in any of the clinical trials that related to Prolift?

A. No, I did not.

Q. Do you know what the TVM Group is?

A. Transvaginal mesh, yes, sir.

Q. That's a group of doctors in France that developed the tools and technique that became part of the Prolift device?

A. Yes, sir.

Q. The studies done by the TVM Group were published in the medical literature for any doctor to be able to see, correct?

A. I believe so.

Q. You would agree that the TVM Group looked at different meshes to use for their transvaginal prolapse repairs, correct?

A. I believe they did. I would have to see the actual paper you are referring to, but I believe that is correct. I think you had Gynecare mesh or Gynemesh, I think you had Gynemesh PS. And then

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later it was ULTRAPRO, which I think it became Prolift+M.

Q. The TVM ended up selecting the Gynemesh PS as the most appropriate mesh for use in these repairs, correct?

A. For their product, yes, sir.

Q. Then Ethicon began working with these group of doctors in France in the TVM Group to develop the tools for the Prolift kit in 2003, is that your recollection?

A. I know it was early 2000s, yes, sir.

Q. Even after the Prolift was on the market, TVM Group and many other surgeons followed patients who had received Prolift in a number of clinical studies, correct?

A. They, I know they were following the patients ongoing.

Q. Would you agree that randomized controlled trials have shown that polypropylene mesh repairs provide a better anatomic cure than native tissue repairs?

A. I think that randomized controlled trials have shown that in the anterior compartment, that there is a better anatomical repair. In the Cochran

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review, that just came out not too long ago, they did a meta-analysis, if you will, or review, I don't know if meta-analysis is the right term, of 37 trials that were in the literature that took them up to, what, June of last year in 2015 and these all had to do with meshes that we are discussing, meshes that were on the market back there in this time frame. And that is one of the things that they found.

But interestingly, they also found that if you did a multi-compartment repair, that advantage went away and there was no increased, there was no benefit over native tissue repair.

Q. Which Cochran review are you referring to with that answer?

A. Well, there was a, I think it was one of a series. This one just came out not too long ago. It was by a Dr. Finer as well as Maher, Chris Maher, but I think it was a continuation. I think they said in there, read this as a six-part series of reviews. I have it on my iPad, if you --

Q. If is it Maher like M-A-H-E-R?

A. I believe so.

Q. Was it in 2016?

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A. I believe it was, I believe it was just fairly recently it just came out. I just, I don't remember the exact date but it had to have been extremely recently, maybe in the last several weeks or so because their review encompassed everything that was up to June of last year.

Q. You didn't save any Cochran reviews in either of your Prolift or Prolift+M reports, did you?

A. I don't remember. I don't remember, I'm sorry, I don't. I think you are correct.

Q. What is the most common type of prolapse, is it anterior compartment prolapse?

A. Anterior is definitely -- anterior and then anterior/apical are by far the most common. Most of the time I think when we get a referral, I think the present, the referring docs go, well, it's just the bladder has fallen down and 89 percent of the time they are right, that's what it is. So, yes.

Q. So anterior or anterior/apical prolapse is the most common types of prolapse?

A. Correct.

Q. Is providing a more durable repair a

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benefit for mesh or native tissue in anterior repairs?

A. Can you ask the question one more time?

Q. Sure. Is providing a more durable repair a benefit for mesh or native tissue in anterior compartment repairs?

A. Now, you are talking about just durability only or are you --

Q. Yes.

A. I think, as far as -- I guess I would present a caveat to that that is, at what price. I mean, having an anatomical repair, we now know, is maybe not the same as having a functionally beneficial repair for the patient.

And the issues that you can have with scarification from mesh contraction, dyspareunia, chronic pain and so forth, to me you have to take that into account, is it specifically beneficial in that patient. But I would say this, if you have got a repair that is durable, that does not have a high morbidity cost, then yes, that's an advantage. That's big.

Q. So hypothetically, if you have got two patients, one has a native tissue anterior

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colporrhaphy without mesh, one has an anterior colporrhaphy with mesh and assume they have the same postoperative course in terms of complications, if the mesh patient's repair is more durable, that's a benefit to her, correct?

A. Assuming there is no increase in morbidity, I would agree with you on that.

Q. Do you agree that in addition to providing a more durable repair in the anterior compartment, the patient satisfaction rate reported in the Prolift medical literature was around 80 percent?

A. I don't remember that specifically, but I'd be glad to look at a specific thing if you wish.

Q. Do you have a satisfaction rate in your mind for Prolift literature?

A. That sounds about right from some of the -- I don't remember that specifically.

Q. 80 percent sounds about right?

A. Roughly, I would certainly, I will say, I will allow it sounds about right, but certainly if I reviewed and found other...

Q. As you sit here today, are you aware of any of the RCTs for Gynemesh PS or Prolift that showed a statistically significant improvement in

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patient satisfaction or quality of life for the Prolift group compared to the native tissue group?
A. There was a study that Ethicon did, I believe, where there was arms in Europe as well as arms in the United States.
I'm sorry, can we go off the record for one second?
MR. KOOPMANN: Sure.
(Recess taken at 10:11 a.m. for eight minutes.)
BY MR. KOOPMANN:
Q. Dr. Raybon, do you remember the question that you were starting to answer when we took a break?
A. If you could please repeat it one more time.
Q. Sure. As you sit here today, are you aware of any of the RCTs for Gynemesh PS or Prolift that showed a statistically significant improvement in patient satisfaction or quality of life for the Prolift group compared to the native tissue group?
A. Now, if you could show me specific studies, I think I could answer it better. The one that comes to mind is the one that involved the

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European arm and I think an American arm there. If that's the one you are referring to, the European arm did not meet Ethicon's internal success rate for the trial. I think the United States arm did meet their internal measure for success but I thought it was only for the anterior compartment. If you could show me something specific, I would be glad to comment on it, but...
Q. But as you sit here today, are there any others that meet the parameter that I just described?
A. That was the big one from Gynecare that I remember. That was, I thought, the real big one that got probably Prolift in over here, I guess, if you will. But as I said, I'll be glad to look at a specific one and review it.
Q. But as you sit here, none others come to mind, no others?
A. None that were that big.
Q. Would you agree that in some patients the use of Prolift was very efficacious?
A. I think that it is a fair statement to say there have been patients with any of the products including Prolift that have done okay.

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Q. Does that include some of your patients in whom you've implanted a Prolift device?
A. Yes, but I will say that I was really concerned about some of the complications that I was having and I felt that they were excessive, so that's why I didn't do more than 25.
Q. Is it true that some of the 25 of your patients in whom you implanted a Prolift had no complications?
A. Some.
Q. Would you also agree that there are many patients who have had a Prolift implanted who have had no complications?
A. I would say that there are patients. I don't know about the many comment there.
Q. So there are patients who have had a Prolift implanted who have had no complications?
A. Yes, sir.
Q. There are patients who have had a good experience with the Prolift device, correct?
A. There are.
Q. Including some of your patients?
A. Including some of my patients.
Q. Why did your report not mention the

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positive experiences and some of the good clinical data about Prolift?
A. Well, I think that it's, basically the price is too high a price to pay, I think, if you are going to have, when you have got, I think it was the trial that you were referring to a minute ago, the adverse event rate in the big Prolift one that was done in Europe and the United States, the adverse event rate was like 65 percent or something there and then even taking it down to, they even felt the need to break it down into serious adverse events, serious, serious adverse events, I don't, it's like at what price. I mean, are you going to treat 100 people and turn a few into pelvic cripples because they can't have sex or can't do the activities of daily living, I just don't think that's an acceptable risk-benefit ratio for most people.
Q. What do you think the rate of mesh exposure is with Prolift use?
A. It is over 10 percent and I think that's being generous.
Q. What's your basis for that number?
A. The basis for that is reviewing Prolift's

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own internal documents as well as my own experience. My Prolift erosion rate was definitely higher than 10 percent and even with my hand-sewn ones with mesh that I was doing, it wasn't that high. And even, I didn't have a rate that high even with Avaulta.

Q. Are you relying on any medical literature for your opinion as the basis for your opinion that the mesh exposure rate with Prolift is over 10 percent?

A. Well, that's internal documents as well as there are things in the literature that support an erosion rate at least that high or higher and that's all in my Rule 26.

Q. Is it fair to say that if the rate is approximately 10 percent, the rate of mesh exposure, that approximately 90 percent of Prolift patients won't experience a mesh exposure?

A. As I said, 10 percent for me, I was being generous. I think in some of Prolift's own documents, it was as high as 17. If we are looking at the narrow problem of mesh erosion, assuming that there is nothing else that has occurred in that patient, then I guess you could say 80 percent or so have not had a mesh erosion.

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But a mesh erosion, while it can certainly be problematic, a pure mesh erosion with nothing else is, if that was all it was, just a little erosion that you could snip out in the office, then you could say, well, you know, that's not as big a deal.

But you have got these women that have this mesh contraction, can't have sexual relations, can't sit, can't stand for prolonged periods of time. That's the real issues. Some of these women we have turned into cripples and there's nothing you can do about it.

Q. Do you differentiate between a mesh erosion and a mesh exposure?

A. I think the end result is you can see mesh in the vagina. I think you can certainly, an erosion would certainly connotate the mesh appearing in the vagina -- we are talking vaginal mesh erosion, I assume, not viscous erosion?

Q. Right.

A. Away from the suture line, whereas an exposure is going to be generally the semantics or more, it's at the suture line, if there was a failure there at the, of the primary healing process. I don't know, I think in all honesty, it's some semantics there. I mean, it's got to be treated in most cases.

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Q. So as you just defined it, a mesh exposure is basically a wound dehiscence where there is mesh behind that wound?

A. That's fair to say.

Q. It is a wound complication?

A. Yes, it's a wound complication or I guess you could even say, was it closed properly or whatnot. I mean, there's lots of reasons that could, I think, affect that.

Q. Is a wound dehiscence possible with any native tissue repair?

A. I have learned in medicine, never say never but I will say in 20-something years, I have never seen that with a native tissue repair.

I'm sure that somewhere somebody has maybe something like a hematoma or something like that I guess could cause a wound dehiscence of a native tissue repair. I have never seen that.

Q. Have you had any of your non-mesh patients in your career experience a wound dehiscence for any type of surgery?

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A. Anywhere in the body, you mean abdominal or vaginal?

Q. Yes.

A. Oh, yes. I mean, any surgeon has had a wound dehiscence, positively.

Q. Would you agree that there are a lot of doctors in the United States who believe that Prolift was safe and effective based on the published data?

A. I would say that there are a pretty good number that felt like it was safe.

Q. And you disagree with those doctors?

A. I disagree with those doctors.

Q. When the Prolift device was introduced, that wasn't the first time surgeons implanted mesh transvaginally, correct?

A. Correct. If I remember correctly, I believe there were some attempts back in the 80s, late 80s with some different materials and I don't think it ended up very well.

Q. When was the first time you ever heard of the Prolift+M device?

A. I think it was several years after I had stopped doing Prolift and I believe the rep at that

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time who was not Mr. Fleetwood, I cannot remember the fellow's name, came by and detailed me on it and brought lunch there. I think in Georgia, because of the volume of procedures and how busy I was, I think I had a target on my back, not just for Prolift but any of the manufacturers that had Prolift procedures -- excuse me, prolapse procedures. And so, even though I had stopped using it, I tried to be informed of what was out there just so I would at least know.

And I think that was the, I'm pretty sure that was the first time or, of course, I could have seen it in a journal there, an advertisement there perhaps.

Q. You have never used the Prolift device in any of your patients, correct? Prolift+M device -- strike that. Let me start over.

A. Okay.

Q. You never used the Prolift+M device in any of your patients, correct?

A. I did not.

Q. Did you ever study the Prolift+M in a clinical research setting?

A. No, I did not.

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Q. Would you agree that in some patients, the use of Prolift+M was very efficacious?

A. To be honest with you, I think that you can say that, just like what you said before, there are some people with vaginal mesh, transvaginal mesh implantation that have done okay. And I wouldn't change that for Prolift+M, I wouldn't lump them all in one basket, but there are some that thankfully have done well.

Q. So you would also agree that there are some patients who have had a Prolift+M implanted who have had no complications?

A. I would say there are some, yes.

Q. And there are patients who have had a good experience with the Prolift+M device?

A. I suspect there are, yes, sir.

Q. What do you think the rate of mesh exposure is with the Prolift+M?

A. I don't think that it is any different.

Q. As the Prolift?

A. Correct, because I have definitely, I have removed quite a number of Prolift products, some of which have been Prolift and some of which have been Prolift+M and I didn't get a feel that in those that

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had an erosion, that there was a much higher or much less erosion rate with the M. I thought they were roughly about the same.

Q. Is that personal experience of yours the basis for your opinion about the mesh exposure rate or erosion rate for Prolift+M?

A. I'd say that's a large part of it. I don't think the, I just don't think anything that I have read indicates that it is any, dramatically different than the regular Prolift. I mean, I think it was a reasonable thought process in the engineering process for how could we maybe make something better, but I don't think it worked out.

Q. Do you think it was a reasonable thought process for Ethicon to try to make a mesh for the Prolift+M device or use a mesh for the Prolift+M device that had an absorbable component?

A. I understand their rationale behind it. You know, one of the things I think that anybody would agree on, that knows a lot about mesh is, less is better, less is better, less is better. And I think that has been reflected in the meshes that you see on the market today. We have gotten lighter and lighter and lighter.

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The pore sizes from early on have now, generally across the board have all been very large, macroporous there. You know, we have not had anything on the market to my knowledge since the IVS tunneler and so forth that had a microporosity to it.

And I think that's just been the -- what was your original question? I'm sorry, I'm getting off subject.

Q. She is going to have to read it back to get it exact.

A. My apologies.

(Record repeated.)

A. Yes, thank you. I think that was during the process of evaluating, I think that, you know, that's a reasonable thing to look into.

Q. It was a reasonable thing for Ethicon to look into to use the ULTRAPRO mesh for the Prolift device?

A. Yes, I think it should have been probably done in a more, instead of just put on the market, I think it should have been studied a little more. But I think, if your question is, and your question, to narrow it down is, was that a reasonable thing

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for them to look at, absolutely. I think it should have been looked at in a more, a clinical controlled setting than just released on the market because unfortunately I don't think it panned out. I don't fault them for trying to make something better because obviously there was a problem. They had a concern about some of the issues there that were, they were seeing with mesh banding and scarring and retraction and so forth.

So by decreasing the amount of mesh that is there and putting in a monocryl or some other absorbable suture component, it maintains some of the handling characteristics that surgeons would appreciate there. So I think on paper, and their R&D, I think it was, you like to see R&D people come up with new ideas and I think that was a reasonable one but I think it should have been studied before it was turned loose.

Q. What sort of testing do you think that Ethicon should have done in the Prolift+M device before they introduced it to the market that they failed to do?

A. I think what they should have done is they should have had a controlled clinical trial where it

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was put in and followed there and these patients followed to see truly did they have an improved outcome with less morbidity.

Obviously, Ethicon was very concerned about it because they were concerned about their morbidity that they were seeing and so in an attempt to decrease that, they came up with this. But I don't think you put it on the market and then get your information. I think you should get your information before it goes on the market.

Q. How many patients should they have enrolled in this study?

A. That's a very good question, sir, and I'm not going to represent myself as a statistician there. I think that's a question best left for somebody else to be able to determine a difference.

Q. What sort of followup would you have liked to have seen with these patients in this clinical study?

A. I'd say definitely, I mean, I think twelve months is absolutely the positive lowest number. I mean, it should be more than that. It should be three years or so, I think, would be kind of what I would be interested in.

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In a trial I was recently in, that's what we went with, was three years and we actually ended up, the company graciously actually ended up pushing it to five years.

Q. Five years before it went to market?

A. Well, it's not even on the market yet. It is still going through the FDA. This company wisely, in my opinion, also avoided the 510(k) predicate process. This is a full-blown trial that's going, that's percolating its way through the FDA.

They got it 510(k) approved but that's at the behest of me and multiple others. We said, you are a fool to release it under the 510(k) process. And they actually listened.

And so this has not been released. And anyway, so it was going to be three years and then the company, we actually are going to have five-year data before it hits the market.

Q. Who is this company?

A. This was AMS, then slash Astora. This is the TOPAS, T-O-P-A-S, trial which is a slang for fecal incontinence, it is a polypropylene sling. I am hoping that, I recently got in communications

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with them, I hope that all that we had worked on is not lost with Astora's closing. I hope somebody else will pick it up because it is actually looking pretty good.

Q. What was your role in this Astora/AMS/TOPAS trial?

A. I was one of the twelve primary investigators, there were twelve sites in the country. There were six urogyn sites as well as six colorectal sites. This sling is for fecal incontinence.

Q. So it is not a pelvic organ prolapse sling?

A. Well, some would argue that it is. You know, Hans Peter Dietz thinks, he is a fellow in Australia that has kind of, quote, invented pelvic floor ultrasound. He thinks that such a product is incredibly important to pelvic organ prolapse because it addresses the genital hiatus which is not something that we address with our current procedures.

And so it is important for your, maybe your most distal level of support. But the trial was set up not to look at that as a primary end

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point. The trial was set up to look at it for fecal incontinence.

Q. Is there a specific medical condition that causes fecal incontinence that this sling is designed to treat?

A. I guess you could use it in a most analogous manner to, a sling for urinary incontinence there. Certainly you have different reasons and sometimes multiple reasons in the same patient. Someone leaks urine.

You can have a, quote, nerve problem, overactive bladder or you can have a weakness, which is I cough, I sneeze, I laugh, I leak, which is what a TVT is designed for. So really what this, in my mind, what this has been designed to do is to address a somewhat analogous weakness in the lower rectum proximal to the anal sphincter there.

There are some of the pelvic floor muscles that basically form a natural sling that goes around the rectum and this seeks to recreate that.

Q. Is it implanted in an open procedure?

A. No, it is an implanted transobturator posterior anal sling.

Q. Is it implanted with trocars and cannulas?

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A. It is implanted with trocars and not cannulas but the arms are sheathed.

Q. Are the trocars passed blindly?

A. The trocars are passed blindly. The difference is, and I can't really show you without a pelvis is you are not going deep into the pelvis. I hate to say it is right beneath the skin because that's not true as well, but when you pass it through the obturator, you can put a finger in the vagina on each side and you can palpate the trajectory of the trocar until it passes the perineum and then the thing that is most different is, this is really outside where most of the muscles are and the nerves and so forth.

Q. Is it made of polypropylene?

A. It is.

Q. Is it made of the same polypropylene that's used in AMS's pelvic organ prolapse products?

A. Yes, it is, like what was once Elevate, that sort of thing.

Q. Do you think the AMS pelvic organ prolapse transvaginal mesh kits are defective?

A. I think that the arm ones, the Apogees and Perogees of the world are defective. I don't think

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a transobturator approach for that problem is the way to go.

Q. Do you think the polypropylene in AMS's pelvic organ prolapse transvaginal mesh kits degrades?

A. Yes.

Q. Why is it that you are okay with this TOPAS product that contains the same polypropylene?

A. Because, first of all, it is -- let's see, it is really hard to, if I had a model I could certainly demonstrate it to you. But you are familiar with probably in your preparation for this the use of mesh for hernia repair.

You know, it's been around, polypropylene or a mesh was used, I think, what, since the 50s when they created the mesh and then they used to sterilize it on the back table in the OR in boiling water to put it into patients. So it's been around a while there.

So a lot has happened with the development of that mesh. But, of course, in a man, a very common hernia repair is an inguinal hernia repair and so I think that while it has been fairly successful in reducing recurrences of abdominal wall

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hernias, there have been some problems, especially with some of the thicker meshes that were out previously that don't have the elasticity or are too stiff for abdominal wall.

I guess my point is that it is put in a somewhat similar location where a hernia mesh would be put but on the bottom of the pelvis. We are not going in along the vagina. We are not going in towards the sacrospinous ligament where the pudendal nerve is there. We are not coming along the pelvic wall where the obturator nerves and vessels are.

There is very little in this area that can be damaged. So that is the difference.

In addition to that, the mesh is not immediately in juxtaposition to the rectal mucosa. You actually have a fairly thick band of the levator muscles in between the mesh and the mucosa. So with vaginal mesh, you have your vaginal mucosa and there's your mesh.

With this, it's going to be something like, there's your rectal mucosa. It is a much thicker area.

That was a concern in the start of this trial. What you just said was a concern. But it

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demonstrates wholeheartedly why you have to study these before you release it to the real world because we have not seen, as of right now, there have been, and I assume somewhat confidential in here but we have 152 that have been implanted around the country. As I sit here today, there has been zero mesh complications there.

I think it truly has, it demonstrates that it is going to matter how mesh is implanted and the location. But it just -- that was one of our concerns, are there going to be some of these things that you and I have been talking about.

The patients were thoroughly consented. It was reviewed, all of these things were reviewed by the institutional review board.

The patients knew, we obviously had some discussions because when we started this trial, some of this mesh litigation was going on there. But you also have to look at, pelvic organ prolapse can be a very functional thing.

I think if you or I were leaking stool, which is, I would argue, a little rougher to deal with than leaking urine. They are both horrible. But I think you and I would both agree that stool

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leakage is -- the risk-benefit to getting into a trial is much different, especially if someone is so worried about it or scared about it or at the point that they are considering a colostomy.

Q. Do you think that the polypropylene mesh in the TOPAS sling will degrade in the human body?

A. I think that there is nothing that is inert, so, yes, I do think it will.

Q. No surgical meshes that you are aware of are inert?

A. I think that -- I don't know of any that are inert in the body. I mean, you can have, you know, I was a chemical engineer and have a degree in chemistry. And so I think we could talk about being chemically inert, physically inert, but in the body in that location, I don't -- I think there's very little that is truly inert.

Q. Do you think the polypropylene mesh in the AMS prolapse transvaginal mesh kits is carcinogenic?

A. That, I don't know.

Q. Do you think the polypropylene that's used in the TOPAS sling is carcinogenic?

A. I don't, no, I don't -- I'm not aware, that has not been the source -- excuse me, that has

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not been the subject of a lot of my review. I think there are some people that have concerns because of the breaking down, is that a potential thing. I think they are looking at that. I don't think anybody has any idea on that right now.

Q. But you are aware of some people who have concerns about potential carcinogenicity of the mesh used in the TOPAS sling?

A. I'm not aware of that, no.

Q. You just said that you are aware of some people with concerns about carcinogenicity.

A. I'm sorry, I think in general as this litigation has unfolded over the last five, six, seven years, whatever it's been, that as it has become apparent that, I remember being told, for example, with Bard, oh, no, this polypropylene is inert.

Well, you know, it wasn't. It is not inert. There is definite irrefutable evidence it is polypropylene that we were using in that mesh that is not inert.

And so then the next question some people have had with polypropylene in general, okay, not just with TOPAS but in general is that if it is

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breaking down, is there a concern over cancer. I think that there's been a concern with lots of things that have been implanted in the body at one time or another with breast implants, so forth and so on.

So I am not aware, to get back to your question, of any specific concerns at this time regarding the carcinogenicity of polypropylene. I know I have heard some people verbalize it but I have not read any data to definitively answer that or address that question.

Q. So you have heard some people verbalize a concern about potential carcinogenicity of the polypropylene that's used in AMS's pelvic organ prolapse kits?

A. And polypropylene in general. I'm sorry, not their kits, in general, but I mean, in polypropylene in general.

Q. How many of these TOPAS slings have you implanted?

A. Ten.

Q. What did you do to satisfy yourself that there is no real carcinogenicity concern with the TOPAS slings before putting them in ten of your

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patients?
A. Well, has anybody? I guess, I don't know of anybody who has done that. I mean, you could argue with this Diet Coke I'm drinking, is that carcinogenic too. I think you can ask that question about anything we put in our bodies. I don't really know how to answer your question more than that.
Q. Is the answer you have done nothing to satisfy yourself that the TOPAS sling, the polypropylene in the TOPAS sling is carcinogenic?
A. I would say that I have done a review of the literature in regards to polypropylene and at this time I am not concerned that it is carcinogenic but I have an open mind and as new data comes to mind, I will reevaluate my position.
Q. Would the same be true for the polypropylene in the Prolift and Prolift+M devices?
A. Yes.
Q. Did you have any sort of design input on the TOPAS sling? Was this sort of an open dialogue between you and the manufacturer?
A. No, this was all one fellow that came up with the concept. Originally, it had been attempted at a, believe it or not, a TVT-type of approach --

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MR. HILL: I know that certain areas of this you are entitled to go into. But I want -- he's got to be very careful as far as confidentiality in this ongoing trial. I am sure you have a confidentiality agreement there.
THE WITNESS: Yes, sir.
MR. HILL: I don't want to step outside the bounds of that if we could. So generalities, I'm comfortable with, but specifics, I think we are getting a little bit close.
BY MR. KOOPMANN:
Q. I don't want you to violate any confidentiality agreement but I have to rely on you to know what that agreement is and what you can and can't discuss.
A. Yes, sir.
Q. So if you can't answer one of my questions because of confidentiality reasons, just say so, okay?
A. Yes, sir. I will just say, it was one guy's idea and AMS was the company that jumped on it.

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Q. Did you feel comfortable talking to the company about ideas you had with respect to the device?
A. Yes, I certainly -- I don't remember any concerns that I had. The concept of the device, I remember the fellow that designed it and had done quite a few himself and it was presented at a meeting, IOGA meeting I attended in Cancun several years ago. So I was familiar with the concept of the device for several years before the study even started.
And so I don't remember any specific concerns that I had. I certainly had no input into the design or the procedure there.
Q. Is the TOPAS sling something that you are excited about based on your review of the literature and your experience with it so far?
A. Thus far, I am excited about it. I am encouraged. I feel like it's probably been one of the, I have to give, in my opinion, kudos to that company for doing the trial in this manner. I feel like it was well-designed and done.
Q. Is the TOPAS sling just totally made of polypropylene mesh?

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A. It is.
Q. It doesn't have any sort of biologic component to it?
A. Not at all.
Q. Did you ever suggest to AMS or the people that you were working with there that they look into PVDF for use in this TOPAS sling?
A. No, I did not.
Q. Did you ever suggest to AMS or the people you are working with there that they pursue or look into possibly some biologic material for the TOPAS sling?
A. No, I did not.
Q. Did you ever use Gynemesh PS sheets?
A. I did not. At the time I was doing a lot of that, we had a, for lack of a better term, preferential agreement, if you will, with CR Bard products and so at that time it was Pelvitex that I had used more as a freehand sewn.
Q. Did you ever use Gortex in sacrocolpopexies?
A. No, sir.
Q. Why not?
A. Gortex, I think it had some problems early

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on in using it that way. Just like with, I think they even used Teflon or something at one point. But no, I did not use that.

Q. Have you read literature that indicates that the use of Gortex in sacrocolpopexies leads to a higher erosion rate than polypropylene mesh?

A. I seem to remember that, that I think that was the issues with those, with the Gortex and I want to say it was Teflon that was used. I have never used any of those as a mesh for sacrocolpopexies.

Q. How many women have you treated that had a Prolift implanted but that was implanted by someone other than yourself?

A. I couldn't answer that question. I don't know.

Q. Maybe I should ask it differently. How many women have you treated for what you believe to be a mesh-related complication who had a Prolift device implanted but by somebody other than yourself?

A. The vast majority of those 75, certainly -- and you are saying these are ones, complications that I have treated?

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Q. Yes.

A. Out of those 75, I think ten were probably mine. All the others were by somebody else.

Q. So of the 75 women who had a Prolift device implanted and had a mesh-related complication that you have treated, ten of those were patients in whom you had implanted the Prolift device?

A. I believe so. If anything, that number is a little high. But I did not -- we didn't track things like that at that time, I can't give you -- that's the best guess I can give you.

Q. For these 75 patients, were those patients who you removed some portion of the Prolift mesh from them?

A. Yes, sir.

Q. How did you know it was a Prolift mesh in those patients?

A. First of all, with any of these products, Avaulta, Bard, Apogee/Perigee, whatever, any of these products, they all have their own little idiosyncrasies to them. And by that I mean, there may be some slight deviations on how they are implanted and so forth there, shakes may be a little different and so forth, which is one of the reasons

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that the FDA I think wisely said, you should get device-specific training. But I digress.

Before I would go in and take somebody's mesh out, I would get a copy of the operative note. I wanted to see, had there been any issues with the device being implanted and I would also get a copy of the implant sheet because I wanted to see what was put in. Some of the patients know. Others do not, they have no idea.

Q. Where would you get the operative report and the implant sheet in those cases?

A. From the hospital. Sometimes it's a pain in the rear if it's way out of state or whatever and some of them have been long enough ago that they are gone, you can't get them.

Q. Is there any objective data that we can look at to verify this number, this 75 number?

A. There's really not, just we had been through, I think I'm on my third EMR now, electronic medical record and unfortunately before then it was paper and then the systems that I have had, I think all the EMRs lack something in functionality.

Q. Do you record in your medical records which specific product it is that you are removing a

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part of?

A. Yes, I do. But there's no way to specifically search for that.

Q. How many of those 75 patients who had a Prolift and you removed some portion of it were referred to you by plaintiffs' attorneys?

A. Not that many. I'm trying to make sure I don't get confused with the IMEs that I had performed because I did not treat those patients.

Q. Sure.

A. But I've had, I don't know, three or five, somewhere in there, total.

Q. Since you were deposed in the Wise versus Ethicon case on November 30, 2015 --

A. Yes, sir.

Q. -- have you calculated the number of times you have explanted a Prolift+M mesh from a patient?

A. Since Ms. Wise?

Q. Since that deposition day --

A. Since that deposition day?

Q. Since that deposition day, have you made that calculation?

A. I think it's been one there and I think it's been one Prolift since then. It comes in

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spells and I'm pretty confident that one was a +M just because it was one of the later implantations.

Q. So you are saying you have done one Prolift or Prolift+M explant since November 30, 2015?

A. Yes, sir.

Q. I think in that deposition you said you didn't know if you had ever explanted a Prolift+M device?

A. Yes. And her, I got --

Q. I don't want to talk about her.

A. Since then, you are right, I think I did say that. But since then I still do, I request the records and so forth and I guess I'm just a little more in tune to that question, figuring it would come up again. So I do know I have done one since then.

Q. So as you sit here today, since you didn't know how many or didn't know, I think you said, any that you had done at that time, Prolift+M explants, is it fair for me to understand today that, as you sit here today, you believe you have done one Prolift+M explant?

A. Since that deposition, that was your

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question?

Q. I want to know the entire universe, how many times have you explanted all or part of a Prolift+M device.

A. As I said, it would be very difficult for me to go back. There's no objective way I can go back and review that. I just know it's been 75 at a minimum of removing Prolift products.

Q. Whether it is Prolift or Prolift+M?

A. Prolift or Prolift+M.

Q. What makes you think that the Prolift or Prolift+M explant you have done since November 30, 2015 was most likely a Prolift+M device?

A. Because I got the implant sheet.

Q. You remember it saying Prolift+M?

A. Yes, I do. It's funny, it is just like all types of surgery, it seems to come in spells. I mean, I won't do a mesh revision for a month or two or three and then I will have, it seems like that's all I'm doing for the next few weeks.

Q. Have you ever received any communication from a third party or plaintiff's attorney asking if you would be interested in seeing patients on a contingency fee basis?

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A. No, I assume -- I don't know because I'm not even sure what you are talking about.

Q. Have you ever agreed to see or treat a patient with the understanding that you would be compensated with a flat fee or contingency fee from a law firm or medical funding company?

A. No, sir.

Q. Do you recommend conservative treatment before agreeing to remove mesh from a patient?

A. Yes, sir, if it's appropriate, yes, sir.

Q. That would include topical estrogen?

A. Yes, sir. In all honesty, by the time they see me, the time that topical estrogen is going to work is probably long gone.

Q. Are you saying that because you have a lot of patients maybe in rural areas who have seen a local primary care provider who maybe suggested topical estrogen, it didn't work and that's why they are coming to see you?

A. I think, first of all, I would say, you have to qualify it a little bit more for me, is this a really big erosion or is it just a small, little erosion. I think that if it is a small, little erosion and it's been there for a few years, I don't

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really think at that point estrogen is going to work.

Now, I will discuss it with a patient and say, we can try it. At that point, they have already had it for two or three years.

I had one lady last year that was kind of similar to this. She was having trouble, was having dyspareunia, if you will, and then, got divorced or whatever and so she was not sexually active. Now that she became sexually active again, two to three years later, it was now a problem and she wanted it to be fixed.

So at that point I really didn't think estrogen was going to work. I mean, the erosion site, the area was too mature, if you will. But I offered it to her. I don't see any problem with doing it.

A lot of my vaginal surgery cases, especially menopausal women, if things are dry, I want them to try it anyway just as a prelude to surgery. Certainly, I think -- I run down all the options with patients.

Q. If a patient comes to you with a mesh exposure, do you always remove the entire mesh or

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just what you think is the offending portion?
A. I think you would have to qualify that a little bit more for me. What is her complaint? Is it just the fact that I'm having a discharge, is it the fact I'm having pain with sex, do I have pain all the time? I think you would have to give me more information.
Q. What if a patient comes in and was having some vaginal pain and discharge and had a 1 centimeter exposure you could see; what would you do in that instance, remove the whole sling or remove the exposed mesh and maybe somewhere around the perimeter?
A. That's a really good question and I'll tell you, my experience in that has been that if they have significant vaginal pain and significant dyspareunia there, then I would say this, during the examination of the patient, if I also determine that there has been a lot of mesh retraction/formation of mesh banding there, then yes, I am going to try to remove the whole thing.
If, however, I examine the patient, I don't find any of that proximal mesh banding or distal mesh banding and it is just a solitary

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erosion but otherwise I can't feel that the mesh is there, then I'm going to do what you suggested, I'm just going to go in and cut that out and try that. But if during the course of the exam I find these other findings, I will talk with them seriously about removing the whole thing.
Q. So if a patient came to you and had a mesh exposure but it was asymptomatic for her but it was causing her partner pain with intercourse, in that instance would you just remove the exposed mesh?
A. Yes, sir, I think that would also be another time to do just that.
Q. Do you serve as a peer reviewer for any journals?
A. No, I do not.
Q. Does your CV that we have marked earlier today as Exhibit 7 contain all of your publications?
A. Yes, sir.
Q. Have you ever published any articles on the Prolift or Prolift+M devices?
A. I have not.
Q. Have you ever done any studies on the Prolift or Prolift+M devices?
A. I have not.

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Q. Have you ever published any articles on Gynemesh PS?
A. I have not.
Q. Have you ever published any articles on the subject of pelvic organ prolapse repair?
A. I have not.
Q. Have you ever written any sort of article, letter or other written document and submitted it to a medical journal to tell your professional colleagues what your opinions are regarding transvaginal mesh use in prolapse repair surgeries?
A. I have not.
Q. Is it fair to say that you have developed the opinions you are offering today and that you have put in your Prolift and Prolift+M reports specifically for this litigation?
A. I'm sorry, can you ask the question again?
Q. Sure. Is it fair to say that you have developed the opinions you are offering today and that you have put in your Prolift and Prolift+M reports specifically for this litigation?
A. I already had my opinion of Prolift before this litigation and I think that if anything, with my further review of literature that was available

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to me already. And then a review of some of Prolift's internal documents, I have refined that. But I already had my opinion.
Q. Is it fair to say that --
A. Or an opinion, excuse me.
Q. Is it fair to say that you developed your Prolift+M opinions that you have set forth in your report for purposes of this litigation?
A. That's a good question. I already had an opinion at that point of Prolift in general and I did not really, I guess, delve into more of the specifics of the Prolift+M until this litigation because I had kind of lumped them all together. I realize that they are different to some degree, but really are still pretty much the same shape, pretty much the same instruments, installed the same way. I just, from a practicality standpoint, as far as the patients go, it is the same as far as I'm concerned.
Q. Is your testimony listed at the back of your Prolift report, Page 28, for instance, accurate and up to date?
A. My testimony?
Q. Yes.

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A. What are you -- where I was deposed or at trial, is that what you are talking about?
Q. Yes, so it lists these cases as cases in which you have given trial or deposition testimony, Sisson versus CR Bard, Dotrinas versus Boston Scientific, State versus blank, some rape case, and then Mary Catherine Wise versus Ethicon.
A. Yes, those are the ones where I have been to trial.
Q. The Wise case hasn't been to trial.
A. I mean, yes, for testimony, yes, sir, I'm sorry.
Q. So the state, the criminal case, the rape case, did you give deposition and trial testimony in that?
A. I gave, I was just asked to go straight to trial, I did not give a deposition.
Q. Was that here in Athens?
A. No, it was in Habersham County which is near Stephens County.
Q. Any other cases that you have given trial or deposition testimony in?
A. No, sir, in regards to --
Q. Anything in the last four years?

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A. No.
Q. Did you give depositions longer ago than four years ago?
A. I was a fellow in Baltimore and there were two cases that my attending there was involved in and one of them I got deposed and it never went to trial. Another one I got deposed and it went to trial.
And then from the time I was a resident, there was two cases that I was named in along with every other physician in the chart at Grady Hospital in Atlanta, and in both of those cases I was dismissed with prejudice once they narrowed it down. And one of those I was deposed and the other one I was, it was settled before I was deposed.
Q. Did either of those two cases involve pelvic organ prolapse surgery?
A. No, sir.
Q. So you have been named as a defendant in two malpractice suits in your career?
A. Yes, sir.
Q. Did you ever have any sort of suspension or revocation of your medical license at any point?
A. No, sir.

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Q. Any sanctions or censure of any kind by the medical board?
A. No, sir.
Q. Would you agree that generally speaking a surgeon's outcomes improve as the surgeon gets more experience?
A. I think that there is a learning curve for pretty much every surgery that's out there and I think that the more you do of almost anything, the better you are going to get at it.
Q. So in a general sense, your thousandth procedure of a specific procedure is more likely to be a success than your fifth procedure?
A. Sounds like a reasonable statement to me.
Q. Mesh erosion can occur after an abdominal prolapse repair using mesh, correct?
A. It can.
Q. Do you agree that transabdominal surgery is associated with increased morbidity compared with mesh vaginal repairs just from the surgery itself?
A. Okay, so you are not talking about mesh specifically, you are talking about just the procedure itself, having to be put to sleep, laparoscopic, abdominal, all those things relative

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to that, you are not talking about the mesh itself; is that correct?
Q. Yes.
A. I think it definitely, that was one of the big reasons we were so interested in this transvaginal mesh approach back in the mid-2000s was because you had the option of some cases in doing it under regional which would bypass some potential morbidity doing it abdominally.
Q. Do you agree that surgical technique appears to play a significant role in the rate of mesh erosion following a transvaginal mesh pelvic organ prolapse repair?
A. There's no question.
Q. Do you practice evidence-based medicine?
A. To the best of my abilities.
Q. What does that mean, that you practice evidence-based medicine?
A. Evidence-based medicine is that you avail yourself of any possibility to become as learned about the topic in question so this may involve attending meetings, this may involve discussing things with other authorities, obviously review of the literature where you seek to get the best, most

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up-to-date information and now, these days, I'm a lot better about judging the information based on the quality of that information, whereas that's one of the things I look for now in the articles and so forth, this is level one evidence, this is level three evidence, so things like that; so where you make your clinical decisions based on the best evidence there is.

Q. What do you consider to be the highest level of evidence? Is it level one evidence?

A. Level one.

Q. What is level one evidence?

A. Level one is typically the holy grail, in most cases it is going to be like a randomized controlled trial. A meta-analysis of a lot of good trials together is also going to be up there as well.

Q. Are Cochran reviews considered level one evidence?

A. I think it is going to depend on the trials themselves they reviewed. I mean, the Cochran review is like what you said, is a review. But in this last one, the one we were just discussing a little while ago, Dr. Maher noted that

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in certain, for this outcome, the evidence was poor, was very low grade to low and then yet another outcome desire was from low to moderate evidence. And so I don't know that you can say that that's a level one. I think that the nice thing about the Cochran is, is they also qualify what their suppositions or assumptions are based on there.

Q. Are systematic reviews, level one evidence?

A. Systematic reviews are up there, especially if they are done by, I think, someone that, Dr. Maher certainly has, I think, a good reputation as far as calling it like he sees it for the good or the bad.

Q. Are Cochran reviews reliable and authoritative in your field?

A. I think Cochran reviews are good sources of information. I think that there are a lot of people that like them. I, certainly it's one of the things I turn to. I wouldn't put anything as the absolute authority.

Q. You have reviewed the 2016 Cochran review by Dr. Maher and others, correct?

A. Yes, Finer, Maher and others.

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Q. Did you also review a Cochran review by Dr. Maher and some colleagues from 2013?

A. I believe that I did. It is not as fresh in my mind, but I believe that I did. They actually quoted that one to some degree in the 2016.

Q. You didn't say either of those Cochran reviews in footnotes of your Prolift or Prolift+M report, did you?

A. Well, the 2016 just came out, so, no, I did not. The 2013, I did not quote that but I bet that some of the other things they reviewed were probably quoted in my Rule 26.

Q. Do you agree that case reports are much lower down on the levels of evidence than randomized controlled trials, systematic reviews and meta-analyses?

A. I think case reports are down on that list, yes, sir. I think they have their place but if you give me a choice between ten case report series and two randomized, well-done, controlled trials of adequate numbers, yes, I am going to take the randomized controlled trial with adequate numbers.

Q. Case reports basically generate

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hypotheses, correct?

A. Yes, I think it's a good -- I think it can raise people's, in the case of something not going well, I think it can raise people's antennas that, wait a minute, we need to look at this and maybe, I think in some cases, provoke people to go, wait a minute, we need to look at this and then it may stir up a randomized controlled trial. I think they have their place, certainly. And the other place they have their place is if you have a very strange complication of some kind where maybe it would be difficult to study but you kind of throw it out there for people to read and go, I will keep that file.

Q. Case reports are anecdotal evidence; is that true?

A. I would consider it anecdotal evidence, because usually it would be like me writing it and just getting it published but it probably hasn't been reviewed by you.

Q. There are some instances where case reports are not peer reviewed?

A. I think that prior to publication, I think that is true. Well, I guess I should qualify that.

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It is always, before it gets in a reputable journal, it is going to be reviewed to some degree by the editorial board, but there are usually, the reputable ones are -- it is very obvious that this is a case review and so forth.

Q. Are you aware that many times case reports are not peer reviewed?

A. Yes, there are certainly some, yes.

Q. Case reports basically report on what happened to a single patient, correct?

A. Right, or a series of those.

Q. Do you agree that animal studies results would fall below case reports in the levels of evidence hierarchy?

A. I don't know about that. There are some studies that you just cannot do in humans and it has to be done in animal studies. For example, the one by Pam Moalli and others where it looked at --

Q. Really, I just need to know the answer to that question, whether you think they are below case reports. I think the answer is no?

A. I don't think it is below case reports. I think there are times where they are very beneficial because you don't have a choice.

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Q. Animal study findings aren't directly transferable to humans, correct?

A. I don't think you can ever say that, no, not directly transferable. It gives you the best educated guess, guess maybe is a little too strong, but as I said, sometimes you just can't do anything else before you try it on humans.

Q. Prior to becoming involved in the pelvic mesh litigation, have you ever gone through and reviewed internal company documents of a medical device manufacturer?

A. No, I have not.

Q. Have you asked for any company documents or depositions that might support an opinion contrary to the ones you formed and set forth in your Prolift and Prolift+M reports?

A. What I did was, when I agreed to do this review and to generate my Rule 26 report, I asked for counsel to provide all documents that they had that came in their possession that related to this litigation. And it is my understanding that's what I got.

I don't think that they asked Ethicon to release just the ones that would support their side.

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I think they got everything Ethicon had to release and that's what I asked for. And I was very adamant when I feel like this law firm has done that well both in this litigation and the other.

Q. I know you said earlier that when you reviewed company representative or employee depositions, you didn't mark the deposition transcripts up --

A. Correct.

Q. -- but did you keep notes on a separate document when you were reviewing those transcripts?

A. No, sir.

Q. Is pelvic or vaginal pain a potential risk of any pelvic organ prolapse surgery?

A. Pelvic pain or vaginal pain, yes, sir.

Q. Could the pain that could result from any pelvic organ prolapse surgery be permanent?

A. It could.

Q. Could it also be severe?

A. It could. I would just say that in native tissue repairs you certainly had those cases that you mentioned, but the degree of morbidity is dramatically less and there's a much better chance that it can be dealt with.

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Q. Is dyspareunia a potential risk of any pelvic organ prolapse surgery?

A. Yes, sir.

Q. Could the dyspareunia that could result from any pelvic organ prolapse surgery be permanent?

A. It could be.

Q. Do you agree that dyspareunia due to narrowing of the introitus of the vagina in a native tissue pelvic organ prolapse repair has been reported in the literature more than 50 years ago?

A. I couldn't comment on 50 years ago but it would not surprise me if such a report exists.

Q. There is a baseline risk of dyspareunia any time you do vaginal surgery, true?

A. Right, or a vaginal delivery or C-section or hysterectomy.

Q. Is a wound complication a potential risk of any pelvic organ prolapse surgery?

A. I think a wound complication is a risk no matter what type of surgery you do anywhere in the body with a synthetic mesh material or not.

Q. Is suture erosion a possibility with any pelvic floor surgery?

A. Are you talking about permanent sutures?

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What are you talking about?
Q. Is suture erosion with permanent sutures a risk of any pelvic floor surgery?
A. Yes, sir. You don't typically see it as much with absorbable sutures but certainly people can break down things at a different rate or incompletely.
Can we have a break?
Q. Of course.
(Recess taken at 11:25 a.m. for nine minutes.)
(Deposition Exhibit 13 was marked for identification.)
BY MR. KOOPMANN:
Q. Dr. Raybon, I am handing you what I have marked as Deposition Exhibit 13. Have you seen this article before?
A. I have. It's been a while, but I have.
Q. This article isn't something you have cited in your Rule 26 reports, is it?
A. I don't think so.
Q. I didn't see it on your reliance list either. Do you think that that is on your reliance list?

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A. I don't know that it is but I definitely have read it. This looks very, very familiar because, as I said, I'm constantly looking and reading, especially in regards to, obviously, my area of interest.
Q. This is a multi-center randomized trial of 374 women who underwent native tissue repair surgeries for apical vaginal prolapse along with a midurethral sling, right?
A. Yes.
Q. The women received either a uterosacral ligament suspension or a sacrospinous ligament fixation; is that right?
A. Yes, sir.
Q. If you will turn to the back, there are several tables attached to the article. I wanted to ask you some questions about Table 8, Adverse Events Related to the Surgical Outcome. Do you see that?
A. Table 8?
Q. The very back. Keep going.
A. Yes.
Q. There are two pages of that Table 8 there in your copy?
A. Yes, sir.

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Q. Table 8 shows that -- it lists the number of participants in each of those two groups, the uterosacral ligament suspension group and the sacrospinous ligament fixation group who had any sort of adverse event; is that right?
A. Yes, sir.
Q. And it shows that 74.5 percent of the uterosacral ligament suspension group had some sort of adverse event, correct?
A. Yes, sir.
Q. And 76.3 percent of the patients in the sacrospinous ligament fixation group had some sort of adverse event, right?
A. Yes, sir.
Q. 16.7 percent of the adverse events that occurred in the sacrospinous ligament fixation patients were serious adverse events; is that right?
A. Yes, sir.
Q. 16.5 percent of the adverse events experienced by the patients in the uterosacral ligament suspension group were serious adverse events; is that right?
A. Yes, sir.
Q. If you will turn to the second page of

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this table, there is a section that says Long-Term Complications. Do you see that in the middle of the page?
A. Yes.
Q. It indicates that 19.1 percent of the patients in the uterosacral ligament suspension group had vaginal granulation tissue at six to 24 months; is that right?
A. Yes, sir.
Q. And 14 percent of the sacrospinous fixation patients had vaginal granulation tissue at six to 24 months?
A. Yes, sir.
Q. And a couple lines down it talks about suture exposure at six to 24 months, do you see that line?
A. Yes, sir.
Q. That reports that 15.4 percent of the patients in the uterosacral ligament suspension group had suture exposure at six to 24 months, correct?
A. Yes, sir.
Q. And 17.2 percent of the patients in the sacrospinous fixation group had suture exposure at

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six to 24 months; is that right?
A. Yes, sir.
Q. So if you add those two complications together --
A. Which ones are you --
Q. For the uterosacral ligament suspension group, that's 65 patients had either vaginal granulation tissue or suture exposure?
A. Yes, sir. I'm sorry, uterosacral ligament suspension group?
Q. Yes.
A. Okay.
Q. And 65 out of the 188 would be a rate of 34.5 percent for vaginal granulation tissue or suture exposure in the uterosacral ligament suspension group?
A. Yes.
Q. Are you aware of any study showing a mesh erosion rate of over 30 percent for Prolift or Prolift+M?
A. I'm not aware of any studies but I think there were some internal documents where they referred to a potential rate as that high.
Q. At the top of that same page we were just

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looking at it says that 6.9 percent of the uterosacral ligament suspension patients experienced neurologic pain requiring treatment; is that right?
A. Yes.
Q. And 12.4 percent of the sacrospinous fixation patients experienced neurologic pain requiring treatment, correct?
A. Yes, sir.
Q. If you add up the number of patients in the sacrospinous fixation group who had either vaginal granulation tissue at six to 24 months or suture exposure at six to 24 months, you get 58 patients; is that right?
A. Yes, sir.
Q. And 58 divided by 186 for the number of patients would yield a rate of vaginal granulation tissue or suture exposure of 31 percent; is that right?
A. Correct.
Q. Why is it that you didn't cite this paper by Barber and colleagues, the Optimal Randomized Trial paper in your reports?
A. The ones that you've mentioned with the vaginal granulation tissue and suture exposure, I

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mean, that is a whole lot different than mesh exposure and so forth. A lot of this stuff can be taken care of in the office there and then you are done.

You can get vaginal granulation tissue. That can happen with a hysterectomy. You can get granulation tissue anywhere in the body, but in these cases you know for sure there's no mesh underlying it, that's the underlying source of it.

So with vaginal granulation tissue such as this, it is a simple matter to just coagulate, take silver nitrate, whatever, and put it on and be done with it. With mesh, if mesh is the underlying source, which I have seen a lot of that underneath granulation tissue, it's going to be the gift that keeps on giving until you get the mesh out.

And so vaginal granulation tissue is something that, I mean, one thing about Matt, Matt designs and runs a very tight ship with most of his studies. I think that his --
Q. You are referring to Dr. Barber?
A. Yes, I'm sorry, Dr. Barber. All of his studies, I mean, there is a strong effort to really, and I applaud him for doing it in this manner. But

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the vaginal granulation tissue, for example, you see that after a vaginal hysterectomy there. You can see granulation tissue on the skin. It's not as common out on the abdominal skin. A lot of times we refer to it as proud skin and you can take care of that easily with coagulation. Suture exposure, you just go in and, I mean, if you see a suture exposure, I have had people come in with that and you kind of grab it, cut it, pull it out and that's it.
Q. You said previously in testimony I think that the 75 patients who had a Prolift that you explanted some portion of the mesh, those didn't include the quick in-office procedures where you trim a little piece of mesh out.
A. Correct.
Q. Is that correct?
A. Correct.
Q. So is it fair to say that there are also instances where if a patient has a Prolift or Prolift+M, it can be remedied in a quick in-office procedure?
A. Absolutely, especially as you recall when I gave testimony a few minutes ago --

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Q. You answered my question. I know you are trying to be helpful but I want to move on.
A. Yes, sir.
Q. Is a recurrence of the prolapse a potential risk of any pelvic organ prolapse surgery?
A. Absolutely.
Q. Is de novo prolapse in the non-treated compartment a potential risk of any pelvic organ prolapse surgery?
A. Yes, it is.
Q. Is infection a risk of any pelvic organ prolapse surgery?
A. Yes, but I would say that in regards to native tissue repair, it is exceptionally rare. Now, of course --
MR. KOOPMANN: I will move to strike everything after yes.
BY MR. KOOPMANN:
Q. You have answered my question.
MR. HILL: I know you want to move along, but he can explain his answer if he feels like he needs to. You can't just limit him to a yes or no answer.
MR. KOOPMANN: I need to get answers

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and I understand he is trying to be helpful but he is giving very long answers and I don't have time to have him explain everything he wants to explain. You can do that after I'm finished with my five hours.
MR. HILL: I think you cannot restrict him to a yes or no response if he feels like he needs to explain that answer further. We all understand the time limitations and he understands that and he is trying to move along. I think we are all trying to achieve that goal.
BY MR. KOOPMANN:
Q. Is bleeding a risk of every pelvic organ prolapse surgery?
A. Yes, sir.
Q. Is organ perforation a potential risk of every pelvic organ prolapse surgery?
A. Yes.
Q. Are urinary problems a potential risk of any pelvic organ prolapse surgery?
A. You mean specifically, voiding problems, infection, what are you --

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Q. Frequency, retention, obstruction, urge incontinence?
A. Yes, sir.
Q. Is it correct that if a patient with prolapse who does not have symptomatic urinary incontinence then undergoes correction for a cystocele, that the correction of the cystocele can unmask their urinary incontinence?
A. That is true.
Q. Have you seen that reported in literature in rates up to like 55 percent of patients?
A. I think there has been a wide range in literature but I have seen that reported in the literature, yes.
Q. Is scarring a potential risk of any pelvic organ prolapse surgery?
A. Yes.
Q. Any time you have a surgery or a penetrating-type injury, you are going to have a scar, that's part of the healing process, right?
A. Part of the healing process.
Q. And scarring is a good thing as long as the scarring is not excessive, correct?
A. Correct. Or where it doesn't impinge on

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something that's vital.
Q. Are scar bands a potential risk of any pelvic organ prolapse surgery?
A. Just with mesh.
Q. What's your basis for that belief?
A. 20-something years of experience having done over, well in excess of 3 or 400 mesh cases, having done well in excess of several, several hundred native tissue repairs. I have never seen bands of scar tissue with native tissue. Scarring, yes, but not these thick bands that are like cables that run from side to side.
Q. Have you ever seen scar banding from a posterior colporrhaphy or a perineorrhaphy?
A. I have never seen scar banding like that. But the scar banding with the mesh and the armed mesh is, I mean -- then you need to ask your question differently because you are not asking it appropriately. Ask your question, I'll answer it.
Q. I think you did answer it.
A. I didn't answer. I answered what you think there but you ask your question appropriately and I'll answer it.
Q. My question was just, have you seen scar

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bands --
A. I'm telling you the answer to that, which is that you don't see it except with bands of mesh. You don't see scar bands running from side to side. So with native tissue repairs, you can see localized scarring but you don't see bands running from one side of the pelvis to the other because that's not how a native tissue repair is done.
Q. So my question is: Is it possible for scar banding to occur with a perineorrhaphy?
A. I just answered that question, asked and answered.
Q. Is the answer no?
A. Right, no. Scarring is possible but not scar bands. Ask the question.
Q. I understand your answer. Just let me ask it.
A. I thought I answered it and we were moving on.
Q. Is scar banding possible with a posterior colporrhaphy?
A. No. Scarring, yes, scar banding, no.
Q. Is vaginal shortening a possibility with any pelvic organ prolapse surgery?

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A. Yes.
Q. Is vaginal stenosis a potential risk of any pelvic organ prolapse surgery?
A. Yes.
Q. Is tissue contraction a potential risk of any pelvic organ prolapse surgery?
A. I don't see tissue contracting. I think you can see vaginal shortening depending on the surgeon's technique and so forth. But as far as contraction, what is it going to contract around.
Q. Does all scar tissue contract as it heals?
A. All scar tissue does contract but you were saying, I took your question to mean vaginal contraction in general. I mean, I don't see what you are asking.
Q. Is nerve damage a possibility with any pelvic organ prolapse surgery?
A. Yes. Well, I would say that it is going to be more likely or possible with something that involves surgery around the sacrospinous ligament. As far as just doing an anterior simple colporrhaphy, I think your risk is minimal if at all.
Q. Is inflammation a risk with any pelvic

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organ prolapse surgery?
A. Can you qualify that, please? There's different types of inflammation. I need to know what you are talking about.
Q. Is any type of inflammation possible with pelvic organ prolapse surgery?
A. I have to give a longer answer. You are going to have acute inflammation which is a normal part of the healing process, that is to be expected with any type of surgery, any type of injury. Chronic inflammation, however, is not the norm, I would say, for a native tissue repair once the healing process is done.
The acute inflammation is expected. The chronic long-term inflammation is not expected after a native tissue repair.
Q. It is not expected after a native tissue repair. Is it nonetheless a potential risk that a patient would have chronic inflammation after a native tissue repair?
A. I would say the only way that could happen would be if permanent sutures were used. If you have an absorbable suture the chance of that happening is pretty much zero.

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Q. Do you use any permanent sutures in your native tissue repairs?
A. Only when going into the sacrospinous ligament, in that area.
Q. What permanent sutures do you use?
A. I've used -- I'd say Ethibond is my most commonly -- there are other brands, Tevdek, Surgidac, so forth. But I think Ethibond is pretty representative of that.
Q. Do you ever use Proline sutures?
A. Oh, yes, and Proline, I'm sorry.
Q. Do you still use Proline sutures in your pelvic organ prolapse repairs from time to time?
A. Yes.
Q. When you do that, do you warn your patients that the Proline sutures degrade?
A. No, not with a solitary Proline suture or so, no, I don't talk about that.
Q. When you implant, when you use Proline sutures in one of your pelvic organ prolapse surgeries, do you warn the patient about cytotoxicity with Proline sutures?
A. I don't.
Q. Do you warn your patients in whom you use

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a Proline suture of an excessive foreign body reaction?
A. Not from a solitary suture, no.
Q. Do you warn your patients in whom you use Proline sutures of a chronic foreign body reaction?
A. Not from a solitary Proline suture.
Q. Do you warn the patients in whom you implant a Proline suture, use a Proline suture of chronic pain from that suture?
A. Not from the suture but, for example, when you are talking about doing a sacrospinous ligament fixation, that is one of the things that has to be discussed with the patient, is, I mean, you could lasso the nerve and then yes, you are going to have -- so in the context of that, yes. Do I specifically say that it's going to be from a Proline suture, I will go, this could be, that could be from any suture if that happens.
Q. Is foreign body response to a suture or graft material a possibility with any pelvic organ prolapse surgery?
A. It's a possibility I think with, well, especially when permanent sutures are used. When you have absorbable sutures, they are ideally going

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to go.
Q. Would you expect that the TOPAS sling that we talked about earlier creates a foreign body response in the body?
A. It probably will.
Q. Do you have any doubt that it will?
A. What's that?
Q. Do you have any doubt that the TOPAS sling would create a foreign body response?
A. I'm sure there will be a foreign body response around it. The question there, and that's one of the reasons we studied it in a meticulous randomized controlled -- excuse me, in a meticulous manner like we did was to get the answer to that question.
Q. Were all of these risks that we have been talking about of any pelvic organ prolapse surgery well-known in the medical community of gynecologists in 2008?
A. You are talking about non-mesh-related surgeries? What are you discussing?
Q. These risks that we have been discussing like scarring, infection, bleeding, organ perforation, de novo prolapse in the non-treated

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compartment, vaginal stenosis, were all of these risks well-known in the medical community of gynecologists in 2008 as being risks of any pelvic organ prolapse surgery?
A. I would have to say yes but those should have been known by the surgeon.
Q. You have never looked at an IFU to learn how to perform a suspension procedure such as an abdominal sacrocolpopexy or sacrospinous ligament fixation, correct?
A. I have never looked at an IFU to learn how to do that, no.
Q. Is a sacrospinous ligament fixation a defective procedure if it results in persistent buttock, vaginal or pelvic pain in a patient?
A. Well, I guess you could look at it that way, but a lot of times that's why we do things that we can hopefully go in there and easily remedy, like leave this permanent suture long so you can identify it and go in and remove it.
Q. You have never looked at an IFU to learn how to perform an anterior or posterior colporrhaphy, have you?
A. You mean, solo -- well, obviously, of

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course not, not with an anterior and posterior colporrhaphy. What would you look at?
Q. You have never looked at an IFU for any mesh before performing an abdominal sacrocolpopexy repair, correct?
A. I don't know, I have read the IFUs for every mesh product that I use. Do I read it every single time, the answer is no.
Q. You have never looked at an IFU to teach yourself the risks associated with native tissue repairs, correct?
A. One does not exist.
Q. So is the answer --
A. No.
Q. -- yes?
A. The answer is I have never looked at one, I'm sorry.
Q. So you have never looked at an IFU to teach yourself the risks associated with native tissue repairs?
A. I have not because one doesn't exist.
Q. Did you learn in your medical training about the potential risk of infection following pelvic floor surgery?

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A. I learned about the potential risk for infection involving any surgery including pelvic floor.
Q. Did you learn in your medical training about the potential risk of bleeding or hematoma?
A. I did.
Q. Did you learn in your medical training about the potential risk of death with any surgery?
A. Yes, sir.
Q. Did you learn in your medical training about the potential risk of vaginal scarring, shortening, contracting or tightening in any surgery?
A. What type of surgery? You said any surgery?
Q. Yes, any vaginal surgery.
A. Any vaginal surgery, I think -- could you name those again?
Q. Did you learn in your medical training about the potential risk of vaginal scarring shortening, contracting or tightening in any vaginal surgery?
A. Could we go, I don't know that I agree with that whole list. Can we go one by one?

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Q. Sure. Did you learn in your medical training about the potential risk of vaginal scarring with any vaginal surgery?
A. Yes, sir.
Q. Did you learn in your medical training about the potential risk of vaginal shortening with any vaginal surgery?
A. Yes. Aside from -- it can happen with a vaginal hysterectomy, but it is extremely rare.
Q. Did you learn in your medical training about the potential risk of vaginal contracting in any vaginal surgery?
A. Well, the contracting, I don't know that it was really that. I mean, we have talked about scarring. We have talked -- I mean, contracting, you don't really, you see some scarring but you don't have things contracting out to the sidewall. So it depends on what your definition of that is going to be.
Q. Did you learn about, in your medical training, a risk of reduced vaginal caliber in connection with vaginal surgery?
A. It depends on the type of surgery. The caliber of the introitus, the entry shouldn't be

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affected by a lot. It depends on, if there is something you are doing specifically, most namely, it would be a perineorrhaphy.
Q. Did you learn in your medical training about potential risk of wound dehiscence or poor wound healing with any surgery?
A. With any surgery anywhere in the body?
Q. Yes.
A. Yes.
Q. Did you learn in your medical training about the potential risk of persistent or de novo dyspareunia with any vaginal surgery?
A. Yes, it just wasn't very high.
Q. Did you learn in your medical training about the potential risk of recurrence or failure of the operation to work in any vaginal surgery?
A. Once again, I'm going to assume we are talking just about prolapse surgery?
Q. Any vaginal surgery.
A. Say the question again.
Q. Did you learn in your medical training about the potential risk of recurrence or failure of the operation to work in any vaginal surgery?
A. Failure of the operation, I mean, I think

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it is going to be different whether you are talking about a vaginal hysterectomy or you are talking about prolapse surgery but in regards specifically to prolapse surgery, yes, there's failure rates.
Q. Did you learn in your medical training about the potential risk of the need to reoperate to treat either a complication or a recurrence after any pelvic organ prolapse surgery?
A. Yes, sir.
Q. Did you learn in your medical training about the potential risk of persistent pelvic or vaginal pain after any pelvic organ prolapse surgery?
A. We did, we discussed it as a possibility. It is just not common.
Q. Did you learn in your medical training about the potential risk of erosion or exposure with permanent sutures?
A. I don't know that I would use the word erosion or exposure. I mean, it's more because -- we certainly learned in the use of permanent sutures in prolapse surgeries that they could be expelled, if you will, there. But once it is removed, it's gone.

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Q. Did you learn in your medical training about the potential risk of mesh erosion or exposure with any surgical mesh-related surgery?

A. Well, in residency back in the early 90s, we weren't using mesh there and that was even before the suburethral slings came to this country. They came to this country in '98, '99, that was several years after my training.

So I will say that I learned about that once the physicians in the United States as a whole started looking more at synthetic mesh usage. We certainly saw it in the suburethral slings and we definitely saw it in the vaginal mesh procedures.

Q. Did you know about the risk of mesh erosion or exposure from the use of a Prolift or Prolift+M product before you ever used a Prolift yourself?

A. I did know that there was a risk of mesh erosion with the use of any mesh device in the vagina.

Q. Do you think the patients receiving a mesh implant in connection with an abdominal sacrocolpopexy should be warned that the implantation of surgical mesh is permanent?

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A. Yes.

Q. You do warn your patients about that?

A. Yes, sir. My informed consent is quite lengthy, the process, I should say.

Q. Do you warn those patients who receive mesh in an abdominal sacrocolpopexy that some complication associated with the implanted mesh may require additional surgery that may or may not correct the complication?

A. I do.

Q. Prior to doing a native tissue repair on a patient to treat her pelvic organ prolapse, do you warn the patient about the potential for serious complications and the effect that they could have on her quality of life?

A. Yes.

Q. Do you warn your native tissue repair patients about potential for pain with intercourse?

A. Yes.

Q. Do you warn your native tissue pelvic organ prolapse patients of the potential for scarring?

A. Yes.

Q. Do you warn your native tissue pelvic

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organ prolapse patients about the potential risk of narrowing of the vagina?

A. I'm sorry, could you say that question again, please?

Q. Do you warn your native tissue pelvic organ prolapse patients of a risk of narrowing of the vaginal wall?

A. Are you talking about narrowing of the caliber, the length, what are you --

Q. Yes, the caliber.

A. The caliber, if I'm doing a perineorrhaphy, then that is certainly something I discuss with them. As far as an anterior repair, I don't really discuss that with them or a posterior repair. But a lot of times a posterior repair may be, unless it is isolated, may be associated with a perineorrhaphy.

Q. Do you warn your native tissue repair pelvic organ prolapse patients of a risk of vaginal shortening?

A. This, once again, you said native tissue repair. Vaginal shortening certainly can happen after a hysterectomy or a native tissue repair, but I tell them that the, what I tell them is that there

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have been cases where this has occurred, but it is very uncommon.

Q. What are the potential risks to the patient from an anterior or posterior colporrhaphy without mesh?

A. So obviously anteriorly, you could have damage to the bladder, damage to the urethra. I have seen some physicians unfortunately do, have damage to the ureters which is exceptionally rare. I have seen fistulas there. I have certainly seen pain with sex afterwards. I have seen pelvic pain. It's just so rare that we see prolonged pelvic pain away from the, that time.

And then, of course, we discussed failure or the need for more surgery, as you mentioned earlier, whether it be the need for more surgery due to failure of the procedure or to fix a complication of the procedure. And obviously there are very similar ones to a posterior colporrhaphy with the obvious caveat that you are not going to damage the ureters and the urethra hopefully.

In that case we have discussed damage to the anal sphincter and the incontinence mechanism and that's also what we discuss anteriorly as well,

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incontinence there of urine.
Q. What are the surgical tools that surgeons use to perform a colporrhaphy?
A. Generally, what I use in the order of use is I do a degree of hydrodistension. I do it slightly differently than I do it if I'm doing it for mesh, but hydrodistension with normal saline and Marcaine and I use a scalpel to make my incision.
And then I will use medicine bombs or Mayo scissors to do your dissection. And then there's also some blunt dissection.
Then, of course, you have to use a needle driver with suture depending if you are doing a vaginal vault suspension like a sacrospinous ligament fixation suspension or you may have to have a special type of suture carrier to do that, and then of course your retractors. I don't know, is that what you meant?
Q. Yes. What are the potential risks to a patient who has a sacrospinous ligament fixation surgery?
A. Sacrospinous ligament fixation, that's probably one of the riskier areas to operate on in the pelvis because you have your pudendal vessels

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there immediately behind the sacrospinous ligament as well as the pudendal nerve. And so, while everything I just mentioned a minute ago is a risk, you can also have damage to those structures, obviously damage to the vessels could result in a significant bleed requiring transfusion or a postoperative hematoma. You could also have a neuropathy if the pudendal nerve or some of its branches are lassoed in the suture, no matter what type of suture it is.
That's one of the things we of course look for right after surgery. If they wake up with intense butt pain, screaming in the recovery room, you turn around and go back.
Q. What additional tools, if any, would you use in the sacrospinous ligament fixation that you didn't just mention in response to my question about the tools you use in a colporrhaphy?
A. There's a -- in the times in the past I have used a Mia hook which helps you take a suture through the ligament. These days, instead of using a Mia hook I am more likely to use a Capio device which is a suture passer device. Once in a blue moon we'll use a Deschamps ligature carrier which is

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one of the older instruments for that purpose.
Q. What are the potential risks to the patient from a uterosacral ligament fixation surgery?
A. Basically, if you take out the pudendal nerve damage and vessel damage there, then it's everything that I mentioned before. There is a, one of the things with the uterosacral ligaments there that you have to watch out for is the ureter there. So in some studies, that has been close to 11 percent in some studies, the ureters have been compromised in some way.
So you definitely want a cysto afterwards which I didn't add to my tool list a while ago but I should have had that on there. Then, of course, the abdominal contents are right above the peritoneum. You have to worry with that procedure a little bit more about abdominal contents injury, whether it is small bowel or what.
Q. What are the surgical tools that you use to perform a uterosacral ligament fixation surgery?
A. Pretty much everything that I just mentioned would be necessary to get to that spot. And of course you would use some clamps like Allis

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clamps to kind of latch on to the uterosacral ligaments and then that's really about it.
Of course, I have a specialized sucker that I use that has an irrigation and a light on it as well to help with elimination; but really, the instruments there that I have mentioned, with the change that they might be a little longer so you can reach up in there better.
Q. What are the potential risks to the patient from an abdominal sacrocolpopexy?
A. Now, pretty much, I'd say to some degree -- now, are you talking in generally or just specific to that? Things that I did not mention for the other things you asked me, anterior and posterior, I was kind of focused right on the procedure itself. I didn't mention the risk of anesthesia, clots, DVT, pneumonia, that sort of things.
Q. Those are present with any surgery?
A. Sir?
Q. Those are present with any surgery?
A. Correct. Okay. I just want to make sure I'm on the same page as you are. So with abdominal sacrocolpopexy, of course, you would have damage to

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your abdominal contents. Just like with the pudendal vessels, if you are doing that, you have the big vessels of the external iliacs, internal iliacs that are there and close by. You can damage the ureter and so forth, and a lot of the other things that I mentioned as well.

Q. What are the surgical tools surgeons use to perform an abdominal sacrocolpopexy?

A. Well, it basically is, if you are doing it just open, it boils down to a scalpel, some retractors and scissors for dissection and a long needle driver there. It's going to be very similar laparoscopically there.

You have your graspers, your laparoscopic forceps, if you will, scissors. A lot of people have some type of energy device that they use if they are doing a hysterectomy at the same time or have a blood vessel or a pedicle they need to take care of. But those are basically it, that and needle driver and suture.

Q. What's the most common mesh material used in abdominal sacrocolpopexy procedures?

A. It's all polypropylene.

Q. Is Gynemesh PS the most commonly used mesh

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material in an abdominal sacrocolpopexy?

A. I don't know that it is or not. I know that Restorelle has climbed up in its market share. But also, for a while there, it was Bard was the number one one. I can't remember the name of it now because I never used it.

But Boston Scientific had one, Astora, which is now shut down, they had one. So I think the answer to your question is evolving right now.

Q. What anatomical landmarks or parts of the patient's pelvic anatomy did the tools that you use in an abdominal sacrocolpopexy pass through?

A. The abdominal wall and all the layers thereof, skin, subcutaneous tissues, fat, fascia, muscles and then peritoneum, pass through to get inside the abdomen.

Q. What about inside the abdomen, what anatomic landmarks do the tools pass through once you are through the abdomen?

A. Once, just for the sake of, I will assume a hysterectomy has already been performed in this hypothetical patient we are discussing and so the first thing, I will just go through my order of doing it. The first thing that I do is identify the

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vaginal vault and I usually have a manipulator in. I then dissect the space between the bladder and the vagina, vesicovaginal space and I create that to the point that I'm happy with it. Then I create the rectovaginal space.

These spaces are potential spaces that we create in surgery and what they represent is the outer layer that we see is the peritoneum which we cut through to get into this potential space. Then I create the space over the sacral promontory by cutting the peritoneum and usually there is a fatty overlay.

We go down to the periosteum and then we open up the right side of the pelvis typically medial to the ureter, the retroperitoneal space on down. So really a lot of it is a fairly superficial dissection.

Q. Is death a risk of any surgery?

A. I would say so. I would say definitely any surgery that involves being put to sleep or receiving an anesthetic. I think there are some minor surgeries you can do in the office where death is almost zero.

Q. Is it fair to say that you take the

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decision of implanting a permanent medical device in a patient very seriously?

A. I do. My consent process lasts over several visits, actually.

Q. Do you undertake a risk/benefit analysis when deciding what products to use in treating your patients?

A. I do.

Q. What do you consider in doing that risk/benefit analysis?

A. What I consider, I consider any available information on that material, whether it's in the literature or if I have gotten it at meetings or from other physicians. We all have people that we look to to give us some guidance at times and not that, it may just be, I talked to doctor so-and-so to get their opinion. So all that factors in.

And then all things being the same, it basically, if I have two products and it boils down to, okay, well, they are both good in my opinion, and it may boil down to what the hospital will pay for.

Q. Is it fair to say you also take into account your past medical experience?

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A. Oh, yes, sir, absolutely.
Q. You also take into account your education and training?
A. Yes, sir.
Q. Have you undertaken that same risk/benefit analysis for every implant you have put in a patient in your career?
A. I would say especially in the last seven years or so, I have been, I would say, very good about it. I think early on in my career, I think that in all honesty, a lot of physicians feel that if something has been sanctioned by the FDA and it is on the market, then it is automatically safe and of course I now know that not to be the case.
Q. Is it true that you want to use products that offer maximum efficacy and safety?
A. Yes.
Q. Do you agree that it is a surgeon's obligation and responsibility to keep current with the medical literature for the types of procedures they are performing?
A. Yes.
Q. And you have done that over the course of your career?

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A. I feel that I have done that over the course of my career.
Q. To what journals do you subscribe?
A. IOGA's journal, what I call the Blue Journal, of course the Green Journal, the Journal of Minimally Invasive Surgery from AAGL, and then every once in a while over here at the hospital, some urologists around, I see some of their, I read some of their stuff but I don't subscribe to it.
Q. Do you agree that it is the surgeon's responsibility to their patients, to their hospitals, to their credentialing boards, to their licensing boards and to themselves to make sure they are familiar with the medical literature for the procedures they are performing?
A. I do. I really do. I think that that is, a lot of that responsibility is on them.
Q. Is it your typical practice to run a PubMed search or up-to-date search to see what literature is generally available on a product before implanting that device in a patient if you have never used it before?
A. If I have never used it before, would I have done that 18 years ago, I don't think I would

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have but I think now being a little wiser in the ways of the world, in the last eight to ten years, yes. I do a lot of up to date searches on a lot of things just to make sure I remain up to date in my thinking.
Q. Is it fair to say that the primary means by which you obtain information about short-term or long-term risks that you counsel your patients about is from your review of medical textbooks, peer-reviewed literature, your education, your training, your discussions with other surgeons and your clinical experience?
A. I think so. I think these days, textbooks are becoming close to the bottom of the list. By the time they are published, they are out of date.
Q. Is it fair to say that you don't rely on medical device manufacturers to tell you how to practice medicine?
A. Absolutely not. I do not rely on that.
Q. You certainly don't rely on a medical device manufacturer to tell you how to counsel your individual patients on the risks and benefits of the procedures that may or may not be appropriate for that particular patient, correct?

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A. I agree with that. I think the medical device manufacturer's role is to be another item on that list that you just mentioned a while ago that I consult. They can be a useful information person that can get information for you and so forth. But you shouldn't rely just on that alone.
Q. There was not a single transvaginal mesh product to treat prolapse for which there were more clinical studies published in the medical literature for Prolift, correct?
A. Say that one more time.
Q. There was not a single transvaginal mesh product to treat prolapse for which there were more clinical studies published in the medical literature than Prolift, correct?
A. I think you may be right on that, yes. I think that is correct.
Q. There are more medical studies done to evaluate the safety and efficacy of Prolift than there were for any other transvaginal mesh medical device used to treat prolapse, correct?
A. I would agree that there's more in the literature on Prolift. I don't necessarily know about the medical and safety, that there's more on

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that in there.

Just with the transvaginal mesh things we talked about, the Cochran review, a lot of the questions, one of the things you just asked, the literature there was very low to low quality. So I don't know that there's great quality on that.

Q. Other than Prolift, Gynemesh PS was the most studied transvaginal mesh product to treat pelvic organ prolapse, correct?

A. I think it definitely hit the ground, it was one of the first ones on the ground. By that very fact, there's more information that you suggest out there.

Q. Are you aware of any valid scientific evidence or data stating that there is another mesh material in the world that is safer and more effective for treating pelvic organ prolapse than polypropylene?

A. I think from reviewing Ethicon's internal documents, I think that they had come up with one they felt.

Q. What was that?

A. The PVDF that you mentioned, or what was their term going to be for it, ProNova.

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Q. Did you consider those internal company documents that you are referencing that in turn reference PVDF or ProNova to be valid scientific evidence or data?

A. I think that a company such as Johnson/Ethicon has a lot of assets at their disposal to look into such things, and I think that certainly some of their key people really felt like it had a lot of potential benefits there. But when you asked me about reviewing internal documents, I didn't have access to those until this litigation. So before the litigation, I wouldn't have had any idea.

Q. Are you aware of any peer-reviewed published data stating that there is another mesh material in the world that is safer and more effective for treating pelvic organ prolapse than polypropylene?

A. I don't know of one right off the top of my head.

Q. What are the risk factors that can lead to a mesh exposure in a patient?

A. I think there are many that fall under different categories. Obviously, one is going to be

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surgeon's technique. You have to mention that.

Number two, what the patient brings to the table. Does she have medical issues that would compromise wound healing? Is she going to be a compliant patient? There's many things there.

Then you have to figure the properties of the mesh itself. I think I have become fond of quoting in the last several years, right mesh, right patient, right surgeon. And for the outcome to be the best, you have to have all three.

Q. Sometimes mesh exposures are asymptomatic, correct?

A. That's correct.

Q. Meaning the patient isn't experiencing any symptoms from it?

A. Correct. She may come in and not even know she has it until she has her annual exam.

Q. Do you believe that the safer alternative design to Prolift is a native tissue repair?

A. I think if you are talking about vaginal prolapse repairs, I think that if you are talking about safety and the potential for extensive morbidity, then a native tissue repair wins hands down when we are looking just at that.

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Q. Do you have an alternative design for the Prolift or Prolift+M devices that you think would have made them safer?

A. I think that the obturator approach, looking backwards, shouldn't have been done there. I think the arm meshes lent itself to asymmetric scarring and contracture which producing a lot of the pain and discomfort and dyspareunia that we see today. So the first thing is I wouldn't do an arm mesh, number one.

They were looking at this anyway as part of their next generation of a tissue that was designed specifically for the pelvic floor. That was one of the things we were looking at, is doing away with the arms or making the arms absorbable where the arms would no longer exist.

I think that's an interesting concept, arms that don't last or go away. But I think, number one, it has to not go through the obturator. Number two, I think what would need to be used is the absolute best material that's available, drawing upon experts that have studied this, that have studied degradation of polypropylene in the body for many, many years. And then the last thing is

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really, really invest in the education of the surgeons.

Q. Are there any other aspects of the design of the Prolift or Prolift+M devices that you think could be made safer?

A. I think those are the big things. I think you get rid of the trocar-based transobturator passes. You put a lot of time and effort into your surgeon training and make sure that they are adequately training and are comfortable, and then use the best material possible. I think those are the big three.

I think some of the other stuff like shape of the mesh, those type dimensions are, you are never going to please every surgeon. I think those are not as important there.

Q. Have you done any testing or experiments to investigate the feasibility or the safety of mesh devices using these alternative design features that you just described?

A. We get some stuff, not with Prolift, no, but I did some stuff similar to what you are asking with Bard there where there was a few cadaver courses, quote, a few cadaver sessions where I was

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the only physician in attendance. I was there with, I remember one specifically where it was myself, some support staff and a Ph.D. anatomist, from I think it was UT, that was present.

We were looking at some designs some of which I had some input into, some I did not. And I have no knowledge if any of those ever went anywhere.

Q. Was that sort of a round table discussion where they would bounce ideas off you and see what you thought about them or was it testing where you actually did some sort of action on these things?

A. Yes, both. I would say that some of the round table stuff was done perhaps at separate sittings where it was me as well as multiple other physicians giving their ideas on things, and then I happened to be chosen for whatever reason for a couple of sessions where I was the only action person; so that in other words, there were several cadavers.

I would put some of their ideas into action, if you will, and then the anatomist would do cutdowns to figure out what I had just done.

Q. Have you ever created a pelvic organ

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prolapse mesh device with this design that you just described where it did not incorporate the obturator approach with trocars, it had no arms, and utilized the best mesh available?

A. I have not.

Q. When you said the alternative design that you would advocate for the Prolift or Prolift+M devices would incorporate the best material available, what material is that?

A. I think that, obviously, there could be some differences to the polypropylene or there may be other things that could be additives to the polypropylene. There are antioxidants that can be added to help with some of these reactions that we are seeing, the chronic inflammatory, the foreign body reactions we have seen.

Those are things, I have a little bit of knowledge and basis of because of my prior experience and, of course, the mesh work. At least on paper, this ProNova or the PVDF sounds enticing. There certainly may be other products out there that I'm not aware of.

Q. Have you reviewed any published medical literature regarding PVDF or ProNova?

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A. Just I have seen what Ethicon's documents were.

Q. So no published materials on that?

A. No, I have not.

Q. Do you know what antioxidants are in the Gynemesh PS used in the Prolift device?

A. Do I know what the antioxidants --

Q. Are.

A. No, not off the top of my head.

Q. Do you know what antioxidants are in the old Promesh that's utilized in the Prolift?

A. No, sir.

Q. So when you say the best material available, you don't have a specific material in mind other than PVDF or ProNova?

A. That's the only specific material in mind. I think that if, sitting down with a bunch of people that could make it happen, biomaterials scientists and so forth, I think I could have some knowledgeable input as to some desirable traits, but no, I don't have a specific one in mind. I can tell you what those traits should be, perhaps, but no.

Q. Have you ever done any testing or experiments utilizing PVDF mesh or ProNova mesh?

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A. No, sir.
Q. Are there any PVDF meshes on the market that you are aware of?
A. Not that I'm aware of.
Q. Have you checked into that?
A. I have not.
Q. If there are PVDF meshes on the market, would you be interested in using those?
A. I'd be interested in looking into it, absolutely.
Q. But you haven't gone out and looked to see if there are any PVDF meshes on the market?
A. No, my knowledge, once again, has just been, what, six or seven months.
Q. I want to ask you the same questions about the Prolift+M. How would you change that to make it safer? Would it be the same things you discussed with the Prolift?
A. I think so. I think there was more of an inflammatory problem with the monocryl being in there than they anticipated. Also, it needs to be, the other thing with the mesh, it needs to be isotropic, not anisotropic like it is.
Q. What isotropic meshes for treatment of

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pelvic organ prolapse are available on the market?
A. I can say that in regards to the Prolift mesh, it is more one-directional there, anisotropic. You want something that has --
Q. What ones are on the market is what I wanted.
A. The Restorelle is more that way than Prolift. But if there is mesh out there that's marketed as such, then the answer is no.
Q. So the Restorelle is more isotropic than Prolift?
A. It is more isotropic, in my opinion.
Q. So you said that Prolift+M mesh has more of an inflammatory response than Gynemesh PS?
A. Especially in the short term because of the monocryl that's in there. It is one of those things, I think, that as I said earlier in the deposition, I think the idea was worth pursuing. I just don't think it should have been pursued on the open market.
Q. So is your alternative design for the Prolift+M, a mesh that has no absorbable component or would it be a mesh with a different absorbable component than the monocryl?

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A. Obviously, I don't think monocryl should be it, with the experience that they had. But maybe there's another one that could be done. Once again, you got to rely on your research to point you in the right direction.
Q. But as you sit here today, you don't have a different absorbable component that you would advocate as safer than Prolift+M?
A. No, I do not at this time.
Q. As a practical matter, do you believe there is any single mesh of any type that can be used appropriately for transvaginal implantation to treat pelvic organ prolapse?
A. In other words, is there one that I would use today?
Q. Yes.
A. First of all, as I told you earlier, I think that the decision to use it can't be undertaken lightly. I think there are patients where it may be appropriate.
Having said that, the ones that I have used most recently was Elevate there. One of the big key differences there that it had was that it was not a transobturator approach there. Of the,

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quote, kits that were left on the market as of this year, I think it was the better of the ones that was out there. But now it's gone.
So I think that today, if I thought that a vaginal mesh procedure was needed, I would probably use the Coloplast equivalent of the sheet of Restorelle and I would probably cut it to fit the individual patient if I thought that was necessary to do. Anyway, that's what I would do.
Q. Are you aware of any randomized controlled trials regarding the Coloplast Restorelle product?
A. Not off the top of my head, no.
Q. There are no studies in patients that show that having a mesh with a larger pore size than Gynemesh PS leads to a statistically significant reduction in complications, true?
A. I don't know of a study where those two have gone head to head. There was -- you are talking about clinically implanted in patients?
Q. Yes.
A. Because there is the Moalli study looking at monkeys there which was, of course, not favorable to Gynemesh PS there. But clinically, I don't know of a study where it 's gone head to head.

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Q. Where another mesh was shown to have a statistically significant reduction in complications where the mesh had a larger pore size than Gynemesh PS?

A. I don't know of a study specifically looking at that question, clinically implanted in patients, no.

Q. As you sit here today, are you aware of any native tissue studies that shows a statistically significant benefit in anatomic correction of prolapse compared to Prolift?

A. Which compartment are you talking about, all compartments?

Q. Sure.

A. You are talking purely anatomical repair?

Q. Right.

A. Nothing else, we are not talking about complications, nothing; you are talking about anatomical results?

Q. Correct.

A. Correct. I think it's been proven in the anterior compartment to exceed, to be superior in that regard to native tissue repair. My opinion these days is that posteriorly there is no

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indication.

Q. Are you aware of any native tissue studies that show a statistically significant benefit in the anatomic correction of posterior compartment prolapse compared to Prolift?

A. What I comment on there is I know of studies that showed there was no benefit to the mesh over native tissue repair. I don't know of a study where that established the converse as being true.

Q. If there was a Prolift study that showed statistically significant improvements in quality of life over native tissue repair, would that reflect a benefit in your opinion for the patients in that study who received the Prolift?

A. With quality of life, you are just talking about --

Q. All else being equal.

A. You mean that, you are talking about everything, there's no dyspareunia; there's no painful contraction; there's no chronic pelvic pain or anything like that?

Q. The question factors all that in with quality of life. So the question is: If there was a Prolift study that showed statistically

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significant improvements in quality of life over native tissue repair, would that reflect a benefit in your opinion for the patients in that study who received the Prolift?

A. That's such a broad term. I would have to look at the specific study you are referring to, because what I'm a little leery of is generalizing to what is quality of life defined as in that study there. And I think that unless you can show me the study you are referring to and to the specific things they looked at in that, then I can't answer the question.

Q. Are there some questionnaires that gynecologists use to assess patients' quality of life?

A. There are. There are several validated questionnaires. I would need to know, generally in the studies, they list which ones they use.

Q. Which questionnaires do you use in your practice to assess patients' quality of life post-surgery?

A. A lot of those people that use those questionnaires like the PISQ and others, the pelvic floor -- I'm sorry. Anyway, those are typically

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more, they are used more in research and academic practices.

Do I sit down and give them these questionnaires, some of which are quite long? I do not. I have not been publishing, I do not do that.

My practice is such that I inquire to my patients about, are you better off before than after; is your sex okay; is your bladder working good. I ask all those questions independently but I don't use those questionnaires.

Q. Are some questionnaires used to assess patient quality of life, invalid in your opinion?

A. I don't know that they are invalid. I think there are numerous questionnaires that have been shown to be, that have been proven to be valid questionnaires. But there's also not one that one size fits all. That's why they have a handful that typically, like at Cleveland Clinic, patients will fill out several, not just one.

Q. But there is not one that you think is just invalid, you don't care what the certain particular questionnaire reports?

A. I don't think I have an opinion. No, I don't.

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Q. Can pelvic organ prolapse be painful for some women?
A. I guess so. I don't see a lot of women complain of pain, but they complain of just severe bother, is the problem. If someone comes in and complains of pain and I really think it's pain, I feel obligated to look for something else going on as well.
Q. Can pelvic organ prolapse be extremely uncomfortable for some women?
A. Absolutely.
Q. Can it be frightening for a woman?
A. Oh, yes. I have some that come in, they just want to know what it is, and then they decide not to do anything about it. Their anxiety is calmed down because they were told it's okay.
Q. Can pelvic organ prolapse interfere with a woman's sex life?
A. It can.
Q. Can pelvic organ prolapse have a detrimental effect on a person's marriage or other personal relationships?
A. It could affect their sex life in a certain way.

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Q. Can pelvic organ prolapse in the form of a rectocele make it so that a woman has to splint to have a bowel movement?
A. It can.
Q. What is splinting?
A. Splinting generally involves either placing the fingers in the vaginal in order to provide a backboard that the stool can push against from the rectal side to be directed towards the anus. In some women, they find it beneficial to press on the perineum, and on a very small subset of women, they find it beneficial to press out on the buttocks.
Q. When a surgeon uses a woman's own tissue as a graft to try to put her pelvic organs back where they belong, so to speak, so there is no prolapse, sometimes that tissue that is used as a graft is also weak, correct?
A. Yes, sir.
Q. That can cause the prolapse to recur, right?
A. That is the theory, yes, sir.
Q. A suture-based prolapse repair can also fail due to suboptimal tissue quality, true?

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A. It can as well as surgical technique, yes.
Q. That's why surgeons began to use mesh to incorporate that into the tissue, to help hold the organs up, right?
A. Yes, sir.
Q. After surgeons started using synthetic materials like mesh as grafts in pelvic organ prolapse surgeries, they started publishing articles about that, right?
A. Yes.
Q. And they wrote the about the efficacy and complications of those procedures, right?
A. Yes.
Q. Those authors wrote about the possibility of mesh erosion occurring in prolapse surgery, right?
A. Yes.
Q. They wrote about those complications long before the TVM group even started their work, correct?
A. I'm not as -- you are talking about right after, in the early 2000s, because the TVM group met around 2004, 2005-ish. So if there were any studies out before then, because you know at that point when

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the TVM group started meeting, Prolift was not released in this country yet, if I'm correct.
So there may not have been much. There may have been some. I just don't remember. Obviously, we would have had some discussion or literature at that point because of the slings, because the TVT had been released in this country.
Q. The published literature showed prolapse recurrence rate after native tissue repairs higher than 30 percent in some studies with some even showing recurrence rates close to 60 percent, correct?
A. Depending on the study, yes. It was 20 to 40 percent, is what I remember. But retrospectively, this was looked at a few years ago at a meeting that I was at. I think it was an AUGS meeting.
Some of that has been called into question based on the definition of the prolapse. I think that's something that's being looked at again critically. But at the time we are discussing, yes, the supposedly high failure rates is what was driving our interest in the vaginal mesh.
(Deposition Exhibit 14 was marked

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for identification.)
BY MR. KOOPMANN:
Q. Handing you what I have marked as Deposition Exhibit 14, it is a study by Dr. Boulanger and colleagues. Have you ever seen that study before?
(Witness reviewing document.)
A. I may have. I've seen a lot of stuff Dr. Cosson has written.
Q. I didn't see it on your reliance list.
A. I feel like this is one of those things, I've got my reliance list, but at the same time things that aren't going to be on there that I have maybe used in my opinion are going to be conversations with other physicians, attendance at meetings and so forth. I really, regardless of whether I'm doing litigation or Rule 26 or not, those things are, that's just knowledge that I have.
Q. Is it fair to say you didn't rely on this study, though, in forming your opinions about the Prolift and Prolift+M?
A. I don't know that that's fair to say because this looks like something I've read. I don't know that I'm willing to say that, as I said,

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for the reason I just told you.
Q. Can we agree you didn't cite it in your reports?
A. I will agree with that. I don't think I did.
Q. This study was an animal study in which the authors placed five different meshes, Vicryl, Vypro, Proline, Proline Soft and Mersutures on the peritoneums of twelve pigs, right?
A. Yes.
Q. In the abstract there you will see in the Results section it says, "Tissue integration was best with the polypropylene meshes which allowed the development of a well-organized, fibrous, mature connective tissue."
Right?
A. One second.
(Witness reviewing document.)
A. Yes, okay.
Q. This isn't a study that you found important enough to cite in any of your reports in this matter, is it?
A. As I said, it's one that certainly looks familiar, and I do a lot of reading out there. I

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have read a lot of stuff that Cosson has done, certainly he and de Tayrac were some of the early adopters of vaginal mesh. So I will agree with you that I did not cite it in my review.
Q. The medical literature on Prolift has evaluated infections associated with Prolift, right?
A. I'm sorry, say it one more time.
Q. The medical literature on Prolift has evaluated infections associated with Prolift, right?
A. I believe so, yes, sir.
Q. Long before Prolift ever came on the market, there were concerns about the ability of a foreign material, any foreign material to potentiate infection, correct?
A. Correct.
Q. The medical literature on Prolift reported very low rates of infection associated with Prolift, right?
A. I believe that is correct. Once again, you are talking about infections at the site of the implant, you are not talking about urinary tract infections or anything of the such?
Q. Right.
A. Okay.

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Q. Are you aware of any studies involving Gynemesh PS that show an increased rate of infection over native tissue repair?
A. Once again at the mesh site, not the bladder or anything like that?
Q. Right.
A. I'm not aware right off the top of my head. No. All of our early concern, a lot of that seemed to get better after all the manufacturers went with the macroporous meshes. We didn't seem to have as much issues with infection as we did like with the IVS toner or the ob tape.
Q. The IFUs for Prolift and Prolift+M were written for doctors, right?
A. Yes, sir.
Q. A prescription medical device manufacturer doesn't have a duty to warn patients, does it?
A. They have a duty to inform doctors of all possible side effects and so forth with their device so that the doctors can inform patients.
Q. What's the basis for your opinion that the medical device manufacturer has a duty to inform doctors of all possible side effects?
A. Because otherwise it basically keeps the

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physician from providing informed consent to the patient. Informed consent, as you know legally, has several components. If you can't advise someone, if you are given this information but it doesn't include all these risks, then basically you have made it impossible for me to gave this patient informed consent.

Q. If you didn't already know about that risk, correct?

A. If I didn't already know about that risk, correct, or maybe there's a big difference in counseling a patient if you go, ma'am, this risk is one in a hundred or one in a thousand or one in 10,000 versus, this is going to happen 20 times out of a hundred. Those type things are things that physicians also need to know so they can put it in perspective for the patients.

Q. If I invent a product tomorrow and you decide to use it in your practice and you know, based on what this product is and how it is going to be used and where it is going to be used in a pelvic floor repair, that dyspareunia is a potential risk of this device, you don't need the IFU for this new device to tell you that dyspareunia is a risk

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because you already know it, correct?

A. I need it to tell me the rates and the severity of it. Just like in Ethicon's internal documents, Dr. Arnaud was like, wait a minute, we need to go back and change this IFU. And he was shot down.

Basically, the response I got from Ethicon's documents was, we have already sent it to the printer; tough. That's just so inappropriate. It gets me, as you can see, it gets me a little bit riled up because you cannot consent your patients properly.

Yes, I know that, we have already established multiple times in your questioning, multiple times, dyspareunia is a risk of vaginal floor or vaginal surgery. What you don't know, unless the physician is told is, okay, the rate of this happening in our trials was this.

Instead, a lot of the wording there was very craftily worded to kind of slide things in under, in my opinion. I think the IFUs for Prolift were horrible.

Q. What is the mesh erosion rate or exposure rate that's reported in the Coloplast Restorelle

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IFU?

A. I don't know off the top of my head. I didn't review that coming to this deposition.

Q. Does it include that information?

A. I don't remember off the top of my head.

Q. Do you think the IFU for the Coloplast Restorelle mesh is adequate?

A. I will tell you this, I haven't seen -- you are talking about apples and oranges here. We are talking about a transvaginal mesh product, Prolift and Prolift+M. To my knowledge, Prolift+M, maybe it was, was used in sacrocolpopexies. If it was, I never used it.

So I don't understand how that's germane to this discussion. We can't talk about apples and oranges and make it meet the way you want to. Let's talk about one thing.

The Restorelle does not -- the Exair product that Coloplast had which was their transobturator vaginal mesh, I never used. So I never read the IFU for that. So if you want to ask me about the Coloplast product, I have to go read that.

But I never did that. So what are we

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talking about here, abdominal sacrocolpopexy? If we are, let's talk about that.

Q. You never read the IFU for the Coloplast Restorelle mesh that you implant in people?

A. I have read that. You misunderstood what I said. They had something called Exair, E-X-A-I-R, that was their transvaginal mesh product. I never read that because I never did it, okay.

Are we talking -- when we are talking about IFUs for Restorelle, the Restorelle I have used is for abdominal sacrocolpopexy. I read it at some point. It's been a while.

I have not had problems with it there. Have I had erosions with it? Sure. I can think of one vaginal erosion that I have had out of the last 200 cases there.

Q. Do all medical devices' IFUs need to report complication rates in your opinion for them to be accurate?

A. Absolutely.

Q. Would you use a medical device without an adequate IFU?

A. I will tell you, today -- sorry, would I use the medical device without an adequate IFU?

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Q. In other words, if you review an IFU before using a device for the first time and you find that IFU to be inadequate because it lacks complication rates, would you still go ahead and use the mesh?

A. And I don't have any other information at my disposal? Assuming that, that I have no other information at my disposal, I am assuming in this hypothetical scenario, I don't have any randomized controlled trials to look at, I don't have any studies in the literature, I don't have any reviews, then the answer is no. I'm not going to use that.

But if there is a long history of the product being used and reputable surgeons and reputable sources and so forth, and there's other sources of information, maybe. But there was no source of other information in this case because Ethicon had all the cards.

Q. What warnings do you think were missing from the Prolift and Prolift+M IFUs that should have been included?

A. I think that's rates of dyspareunia, the rates of severe mesh contracture, those are the ones. The fact that patients can have chronic

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pelvic pain; chronic leg pain where they can't get up and around; dyspareunia; severe mesh erosions requiring major surgeries, multiple surgeries being required; the fact that this mesh cannot be removed in its entirety. The nerve damage was glossed over.

You can't say in your IFU, there's a risk of nerve damage, and then you kind of belittle the importance by adding in, well, this is rare, this is whatever. A surgeon, they see that, then they think, they assume that it is really, really rare.

Who decides what rare is? I think the surgeon needs to be the one to determine that so that they can get informed consent from their patient.

Basically, by not giving adequate information in the IFU or giving adequate information to the physicians, I feel like Ethicon is telling these surgeons, you don't have the knowledge, education or whatever to assume what's significant and what's not, so therefore we are going to give you what we want you to have.

Q. Have you formed an opinion that one particular IFU for a pelvic organ prolapse device is adequate?

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A. No, I have not been asked to do that.

Q. Are there any that you have in mind where you could say, take a look at the IFU for this product, that's an adequate IFU in my opinion?

A. I don't have one off the top of my head, no.

Q. Did you conduct any testing or surveys with the Prolift or Prolift+M IFUs to ascertain whether they were adequate in the eyes of other pelvic floor surgeons?

A. No, sir.

Sorry, can I take a break for a second?

Q. Sure.

(Recess taken at 1:00 p.m. for seven minutes.)

MR. KOOPMANN: Back on the record.

BY MR. KOOPMANN:

Q. Dr. Raybon, I have placed in front of you what we have marked as Exhibits 9 and 10, 9 being your Prolift report, 10 being your Prolift+M report, correct?

A. Yes, sir.

Q. I will ask you some questions about those. Let's start with the Prolift report. You mention on

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Page 2 that one of the reasons you stopped using the Prolift products in 2008 was due to unacceptably high erosion rate, correct?

A. Yes.

Q. What was that erosion rate?

A. It was over ten percent. I had been using, as we discussed earlier, hand-sewn meshes and so forth. And my erosion rate with hand-sewn meshes was down in the three percent range.

And then with this, as I said, I did at minimum 25, and so it was higher than ten percent. And it just got me scared.

Q. There aren't any data that we could look at to verify that that was the rate, is there?

A. No, sir, as we discussed, I have been through three MRs and some of that was PACH.

Q. You also indicated one of the reasons you stopped using Prolift products was that Gynecare did not exercise due diligence in ensuring that implanting physicians were adequately trained.

A. Correct.

Q. Did you feel that you were adequately trained on the Prolift device when you went to that cadaver lab?

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A. I did. I had a lot of knowledge. I had been to a fellowship, I had a lot of knowledge of pelvic floor anatomy and surgeries.

I had already been doing the dissection with free-cut mesh, as we discussed. So I felt I had a good, strong foundation and I got device-specific training by one of their preceptors. So yes, I did feel like it.

Q. On Page 3 of your Prolift report you indicate that, "Ethicon marketed its Prolift mesh devices without first obtaining FDA 510(k) clearance and sold the product for more than three years in the United States without governmental permission."

A. Yes.

Q. What was the basis for that statement?

A. That was in the news.

Q. What news story are you referring to?

A. Gosh, it was, I can't remember, was it the Wall Street Journal or Bloomberg or something? I remember, I think, a buddy of mine even said, hey, check out whichever one it was. And I think it was one of the financial things because they were really -- I think it was one of the financials, either Wall Street Journal or Bloomberg, but it was in the news.

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Q. So is it your opinion that the Prolift was marketed illegally?

A. I will say that they did not get their -- if they didn't meet the requirements of the FDA, is that not illegal? I don't know.

I know I can't ask you a question, but I don't know the legalese and all that. To me, they didn't do the government requirements.

Q. So is it fair to say since you don't know the legal requirements, that you don't know if Ethicon's marketing of the Prolift was illegal?

A. I can't comment on that. I'd have to let one of you guys say that.

Q. You say you have worked with medical device manufacturers in the development and evaluation of pelvic repair mesh products.

A. Yes.

Q. Is that the TOPAS work that you referred to earlier?

A. I have done TOPAS work, Avaulta; Bard was not only Avaulta but it was also slings. I have done some other work with AMS/Astora. I did not do any with Ethicon. I did not do any Boston -- yes, those were the ones.

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Q. What was your role in the design of the Avaulta product?

A. The Avaulta product, when I first got involved with that, their initial Avaulta biosynthetic was in its final stages. And so I was more involved there at the end as, hey, okay, this is the final thing; how does this look; is this going to work good, and so forth.

Now what I call, and a lot of us term, the second generation Avaulta which the trocars were radically changed, the design of the mesh was radically changed, I had a lot more input into that, like at some of these round table sessions as you referred to as well as some cadaver sessions that were geared just to their KOLs, if you will.

Q. Have you ever developed a battery of testing that was to be done on a device during a device's development?

A. No, sir.

Q. When we were talking earlier about your IFU-related opinions of the Prolift and Prolift+M IFUs, are there any standards that you are referencing where I can go and look on the internet look up that particular standard?

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A. I don't know a standard, but this is probably a bad analogy, but who is the guy, the famous Supreme Court guy or whoever that says, I know obscenity when I see it? I think I know a good IFU when I see it.

I don't know that there are standards there. I can certainly go on with you at length about what I think should have been in here, as we have already done.

Q. When you say on Page 3 of your Prolift report that, "In designing a pelvic repair mesh product intended to be sold and implanted by physicians like myself, a reasonable device manufacturer must consider and weigh all of the known risks versus the benefits of a particular design as well as all information known to the manufacturer that may bear on the safety and efficacy of the design including the gravity, severity, likelihood and avoidability of the dangers associated with the design."

Did I read that correctly?

A. Yes, sir.

Q. What is the basis for that statement, that those are the things that a reasonable device

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manufacturer must do in designing a product?
A. As we were discussing earlier, certainly I think that it's been established that anterior compartment mesh does have a benefit in anatomical success. We have discussed that earlier, and I don't disagree with what it has shown. But my rejoinder to that would be, at what cost. The --
Q. All I am asking is what the standard is. Where did this standard come from that we just read? Is there some standard I can look up on the internet?
A. No, there's no standard. That's just kind of --
Q. Your take?
A. It is common sense stuff. These are things you trust the manufacturer to do their due diligence in bringing the design to the market, that these things have been done, addressed the positives and the negatives, and made sure that those equal out or are beneficial.
Q. On Page 4 you talk about your opinion that, "The risks inherent in the design of the Prolift outweigh its benefits for several reasons."
So you did a risk/benefit analysis with

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the Prolift device; is that true?
A. I did a risk/benefit analysis with everything that I can think, probably, whether I absolutely realize it or not, with every device that I use.
Q. Explain to me what risk/benefit analysis you did in evaluating the Prolift and Prolift+M devices.
A. You mean for my own personal patients?
Q. No, in forming these opinions.
A. When you look at the risks and benefits here, you also have to assume that -- one of the biggest things for me is who is going to be doing this. By Ethicon's own internal documents, hey, this is not as easy as we thought. These surgeons are going to need more training, they are going to need more hand holding. Even some of their KOLs said, this is harder than we thought. That was not addressed by Ethicon at all.
Indeed, during the time, the early time, my basis for this is during the early time when Prolift was getting out on the market, they had their own thing that said, okay, we're just going to train X number of people, we are only going to allow

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it to be released to the hospitals that have trained surgeons. We are only going to do this, this and this.
That is not the case. I had firsthand knowledge of that happening there, and that's not what they did.
You can blame it on the individual rep, but it went higher than that because I had personal conversation with a regional manager, who are you going to let do this. This basically boils down to, this is not just for anybody to do. I'm not saying anybody can't learn it with the training, but when you are taking Ethicon's KOLs, you put this device in the hands of Michelle Cosson or Renaud de Tayrac or any of those guys that are fabulous surgeons, their outcomes are going to be different than when Joe Blow Shmo gynecologist gets hold of it.
Q. Would this be true for the TOPAS sling?
A. Absolutely.
Q. Any product?
A. I think for any product that involves this level of complexity. If you develop a new suture driver, needle driver to do suture in surgery, do you need to get training for that? Maybe not, you

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have been doing it for 20 years and this one just clicks, okay. But something of this complexity, of this magnitude, this is a place where Ethicon fell down on the job.
Q. You say it elsewhere in your report that basically you are aware of an instance where a surgeon in this area somewhere was allowed to implant a Prolift device or implanted the Prolift device and he or she wasn't ever trained specifically on the device.
A. Correct.
Q. He or she just had a sales rep present to walk him or her through the procedure?
A. Correct.
Q. Who was that?
A. That was Lionel Meadows in Toccoa, Georgia. That happened less than a week after I had had the conversation face-to-face with the regional manager there.
I raised Cain about it, not only with Ethicon, because I confronted them about it, and the first additional thing was they tried to lie to me about it there, and I called their bluff. And then when they finally admitted, that's when I said,

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well, I think maybe we should part ways as well.
Q. Who tried to lie to you about it?
A. The regional manager. The rep was very uncomfortable talking to me about it. And I got the feeling he was getting a lot of pressure from above, because he was really dancing around it. Ultimately, he told the entire truth there.
Q. How do you know what -- I am sorry, what was the doctor's name again, Lionel what?
A. Meadows.
Q. How do you know what Dr. Meadows' level of training was on the Prolift?
A. Because I asked them. I said, did he or did he not go to one of your training things, which at that time most of their trainings were done down at Celebration there. At that time, he had not been to training.
And I asked the rep flat out, I said, did he or did he not go to training.
No, he did not.
I said, okay, did he attend any other training around or go see somebody do it that I don't know about, which he could have done.
No, he did not.

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I said, so you are telling me he's had no training regarding the Prolift?
Correct.
This is someone, too, I just happened to have firsthand knowledge that wasn't doing these types of repairs. He wasn't doing free-hand-sewn, free-cut mesh. He had no basis for experience.
Now, I'm not knocking the fellow. He could certainly go and learn, anybody could. But it was kind of like -- and I put some fault on him too, don't get me wrong. He should not have done it there. And I didn't even know what I knew now from Ethicon's internal documents. They were like, oh, no, we are not going to let people do this.
I have firsthand, irrefutable firsthand knowledge of that.
Q. Do you have any opinions regarding the adequacy or inadequacy of any training Dr. Jeff Lovinger received from Ethicon regarding Prolift+M device prior to implanting that device in Plaintiff Shirley Freeman?
A. No, I don't know who he is. And I'm not familiar with the specifics of that case.
Q. Do you have any opinions regarding the

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adequacy or inadequacy of any training Dr. Felicia Lane received from Ethicon regarding the Prolift+M device prior to implanting the device in Plaintiff Shirley Walker?
A. No.
Q. Do you have any opinions or adequacy or inadequacy of any training Dr. Mark Aiken received from Ethicon regarding the Prolift device prior to implanting that device in Plaintiff Elizabeth Blynn Wilson Wolfe?
A. No, sir.
Q. Are you aware of any other publications that Ethicon published and provided to surgeons that provided information regarding erosion rates?
A. I think I saw they had a monograph or something, a surgeon's monograph that they would pass out at some of the training.
Q. What did you think of that document?
A. I think it was okay. It still fell short. But the problem with that is I have been to training sessions like that. Unless I give this to you, sir, and I say, okay, did you get this, you sign it.
If you send a subpoena to me, you make me sign for it so that you know that I got it.

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Nothing like that was done. Of course, why would it be?
But I have been at trainings where we gave out stuff like that and the physicians left it on the table. I have seen them leave their books and everything with the DVDs and everything that's there sitting there.
My point there is, the thing, coming back to the IFU, it's going to be in the box by law or regulation, so you know they got it, without question.
This monograph or whatever that I mentioned, there is no guarantee they got it. There's no guarantee they kept it.
Q. On Page 4 of your report you indicate, "The Gynecare Prolift systems require transvaginal implantation of a synthetic polypropylene mesh using specially designed trocars, needles and sleeves."
My question for you is, is there any particular about the trocars and sleeves that you think is defective and unreasonably dangerous about the Prolift or Prolift+M devices?
A. I think that just the fact -- first of all, I think there are problems with all

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transobturator meshes. I think it was a poor approach. And I think the problems there as far as, I think any trocar going through there is not going to be risk-free. And I think that it requires, these risks can be ameliorated by having a well-versed pelvic surgeon do it.

But you are talking about the actual trocar itself?

Q. Yes, not the idea of using a trocar, but the diameter of it, the materials made from it, things like that.

A. No, not the trocar itself, no.

Q. On Page 5 you note, "As the Prolift mesh arms are being pulled through the plastic sleeves, they conform to the shape of the small bore cylindrical sleeves which causes deformation and curling of the arms, altering the shape of the arms at the point of contact with the pelvic sidewall."

Did I read that correctly? ***

A. Yes.

Q. Did that happen with the Avaulta too where it would change shape when being passed through the cannulas or sleeves?

A. We didn't have a sleeve or a cannula

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there, and so the problem there with the Avaulta was such --

Q. I don't need to know what the problem was.

A. Okay, I am sorry.

Q. I just need to know if that happened.

A. I think it happened to some degree, yes.

Q. Did it happen every time you implanted a Prolift product?

A. Yes.

Q. So it happened the very first time you used it?

A. Yes, sir.

Q. And then you used it at least 24 more times?

A. Yes.

Q. You say further down on Page 4 about halfway --

A. 4 or 5?

Q. I'm sorry, 5, about two-thirds of the way down the page, "When the mesh shrinks, the arms of the mesh pull on their anchoring points in the pelvic sidewall, muscles obturator and levator ani, tending to pull these anchoring points and the attached muscle toward the midline."

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What is the basis for that statement?

A. The basis for that statement is obviously a lot of things that I have read, but really a lot of it is my hands-on experience in this matter. That is just what you see.

Q. Have you done any testing to establish that?

A. Establish what?

Q. That when the mesh shrinks, the arms of the mesh pull on the anchoring points in the pelvic sidewall?

A. Seeing it and feeling it with your own hands, I don't need to test that. It's in front of my face.

Q. No cadaver testing or anything like that?

A. How are you going to test that in a cadaver other than implanting it in a patient, killing them a year later and doing it?

Q. So is the answer no?

A. The answer is no.

Q. You go on to say, "It is my opinion that in women with these Prolift transvaginal mesh implants, this pulling on the pelvic sidewall muscles causes pain at rest, during sexual

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intercourse, during defecation and during normal daily activities like coughing, jumping and straining."

What's the basis for that statement?

A. Once again, things that I have read in the literature as well as my own personal experience, you had these arms that run from sidewall to sidewall, and when you examine these and you tweak on them oftentimes I refer to it as a banjo string, a lot of times their complaints are recreated.

Q. So that's what leads you to believe it is the pulling on the pelvic muscle sidewall that causes the pain?

A. Yes, as well as just seeing the severe contracture of the mesh.

Q. You say on Page 6 that, "This bilateral anchoring creates a non-expandable spanning bridge over the rectum which has the potential to obstruct stool passage and cause pain. I have seen several patients present acutely with this problem."

How many patients have you seen present acutely with that problem?

A. Once again, this is a generalization. I have taken out more than just Prolift armed mesh,

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okay, so I have -- I would say I have seen some with all, maybe ten in all, with this specific problem.

Q. Ten patients?

A. Total. Now, I'm also throwing in some Avaultas that have come out, as well as -- probably Avaulta and the Prolift have been the main ones there. But I have seen that.

Q. Are they all anchored at the same points as the Prolift and Prolift+M?

A. Avaulta and Prolift are very, very, very, very similar. Avaulta Prolift came out initially advocating passage of one of the arms through sacrospinous ligament. With the second generation Avaulta, they made that a possibility in response, really, to the Prolift.

Q. You say at the bottom of Page 6 that, "The mesh is static in the Prolift device and does not give according to the needs of the tissues in which it is implanted."

What's the basis for that statement?

A. Once you go in there and grab it with your own hands, once it is seated in place and you go back on these patients, there is nothing there stretching with it. You grab each side of it and

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there's no giving there. So that is probably, even before I started reviewing this, I knew that.

And there are other things where now I have learned a lot more of the technical terms associated with it and so forth by some of Ethicon's internal reviews or internal documents. That is something I appreciated long before this litigation.

Q. Is it fair to say that you didn't have any concerns about the Prolift mesh's ability to give according to the needs of the tissues in which it is implanted when you implanted it in 25 of your patients?

A. At that time?

Q. Right.

A. At that time I did not have the concerns I have now.

Q. You say at the bottom of Page 6, "Additionally, the fibrotic shrinkage further restricts the functional mobility of the pelvic floor organs and restricts the natural movements of the vagina during defecation, urination and intercourse. These conditions cause pain."

What's the basis for those two sentences?

A. I'm sorry, where are you?

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Q. The last sentence on Page 6.

A. Okay. Once again, you read about this, you talk to other surgeons that have this, but probably most importantly, you see it and feel it with your own hands when you operate on these patients later.

Q. In the next paragraph on Page 7 that starts with Number 2, the end of that paragraph you say, "It is my belief that this degradation is an ongoing process that can cause clinical issues years down the road remote from the initial implantation."

What's the basis for that statement?

A. Once again, my own personal experience, having pulled out Prolifts and other armed meshes seven, eight years or more after their implantation. Additionally, there is work, for example, I believe one that I remember was Kloserhalfen stating that this is an ongoing issue, that you have this ongoing reaction to the body, this chronic inflammation. And so that is the basis.

Q. You go on to say in the next paragraph, "The size of the pores in the mesh used in the Prolift devices was inadequate to allow good tissue ingrowth, and this resulted in excessive fibrotic

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bridging, scarification and mesh contraction, which can cause erosion, vaginal or pelvic floor deformation, nerve damage and chronic or permanent pain."

Did I read that correctly?

A. Yes, sir.

Q. What is an adequate pore size in a prolapse mesh in your opinion?

A. You want it to be greater than one millimeter there in size. And if you get greater than one millimeter, you are going to start to limit your potential for fibrotic bridging and so forth, because otherwise you get like one big granulomatous area. So by spreading it out, you are still going to have that response, but those responses aren't going to touch.

So that is going to ideally allow movement to continue to occur, but when they are close together, you get overlapping and bridging.

Q. What is the pore size of the Gynemesh PS used in the Prolift device?

A. Some of them were one millimeter, but there was a lot in a sample size, there was a lot that was not. Additionally, I think when stress is

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put on it, it makes that smaller.
So I think that would help if it just wasn't so anisotropic there, if it had more ability -- but I think when that is happening, the pore size is actually collapsed, then it gets smaller.
Some of that I would say could be the surgeon's technique, too, putting it in. This really should be put in tension-free, but I think that was a concept a lot of surgeons didn't grasp.
Q. So you want a mesh, I think you said that's isotropic or is it anisotropic?
A. Isotropic.
Q. So you want a mesh that is isotropic so it is distensible and can expand with the vaginal tissues?
A. Right, in more than one direction, like just -- you don't want it to be just along the axis of the vagina because things aren't just going to go this way (indicating).
Q. You have motioned forward and backward?
A. Yes, along the axis of the vagina, I'm sorry. So with intercourse or defecation, because the -- I mean, with defecation it is not a straight

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shot down into that area, it is kind of curving in from the side and then coming in. You want that area to be able to give.
Q. What's the pore size of the Prolift+M mesh preabsorption of the monocryl component?
A. Preabsorption, I don't remember. I am sorry.
Q. Do you remember what the pore size is of the Prolift+M mesh to post absorption of the monocryl component?
A. I don't remember exactly. I'm sorry. I'm drawing a blank, all of a sudden.
Q. You said that, when I asked you what the pore size was of the Prolift mesh, you mentioned that some of them were a millimeter, but some were smaller. What's your basis for that statement?
A. There's some internal documents where that was looked at by Ethicon.
Q. You say in Paragraph 4 on Page 7 that, "The Prolift mesh had a serious biomechanical mismatch between the mesh and tissues in the vaginal area."
Are there any meshes on the market used in prolapse repair that you think do not contain a

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serious biomechanical mismatch between the mesh and the tissues in the vaginal area?
A. I think that probably Restorelle comes the closest to this. There was a study with Restorelle, it was a couple years ago. It was presented at AUGS, A-U-G-S, by a physician, it was not Pam Moalli, it was somebody else, where they studied it independently. Coloplast did not fund it. And they found a lot of very favorable changes there.
So I think that is the one that comes the closest to not having a mismatch. But I think that that's something, if you read through Ethicon's internal documents, they talk about now pelvic floor meshes are overengineered, overengineered, overengineered. It is obviously something that was forefront in their mind, even at the start of the Prolift.
Q. Do you think the Prolift mesh was overengineered?
A. It was obviously more than what was needed in the pelvic floor.
Q. In terms of what?
A. Do you really need -- drawing off Ethicon's own experience with abdominal, they used

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to think stronger is better, and they discovered that that was not the case. And the vagina is even much more unique than the abdominal wall.
So looking at some of their strength studies, it was just much, much stronger than it needed to be. It could have been a little more pliable and soft and being able to give, because it is just a unique part of the body. There's a lot going on in this small area that you don't have in the abdominal wall.
Q. Do you continually try to improve as a surgeon?
A. You do.
Q. Would you agree that just because you might be a better surgeon tomorrow than you were today doesn't mean you were not a good surgeon today?
A. (Indicating affirmatively.)
Q. You say on Page 8, the bottom of Paragraph 5 that, "The deformation of the mesh," and you are referring to the deformation of the mesh after insertion of the mesh via the cannulas and trocars, "it impedes the body's ability to incorporate into the material, and contributes to excessive fibrotic

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reaction, scarification and shrinkage and pain."
What's your basis for that statement?
A. First of all, it is not just the mesh, it is the mesh arms. I think you just said mesh, but what we are referring to here is the mesh arms.
From my knowledge of mesh complications in general, you want the mesh to be nice and flat, and when the arms are curled, basically this is happening like this, and so you have doubled the mesh density in that area. That's going to impede your tissue ingrowth and whatnot. And so even if you had an adequate pore size in those, now you have just potentially made it much smaller.
Q. Before you implanted your very first Prolift device, did you recognize that there was some possibility that that piece of surgical mesh may need to be removed due to some complication?
A. That's a really good question. I think it is a really fair question.
I don't know that at that time, the way a lot of us had embraced it or it was presented to us, and not just by Ethicon, by all companies, that a lot of reference was being made to, this has done very well in hernia repair and so forth. We didn't

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know or realize that some of the hernia meshes had to be removed at times.
So I guess it was in the back of my mind, I don't know that it was forefront, as it wasn't with a lot of other surgeons. No, I don't know that anybody thought about that.
Q. Before you implanted your first Prolift, you knew how the device was designed to work, in other words, that tissue was supposed to incorporate into the pores of the mesh?
A. Correct.
Q. You knew where the mesh was going in the body?
A. Correct. To further answer your last question, the thing that was unique about this was, I think a lot of us that did it at first had done hand-sewn free mesh, hand-cut mesh. The difference was these arms, and so one of the things was having the arms on here really changed a lot.
Q. How many of the 25 women who you implanted with a Prolift device had a mesh infection?
A. I don't remember any that had, someone that I thought was a mesh infection.
Q. Do you need to go off the record?

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A. No, sir, thank you.
Q. On Pages 14 through 18 of your Prolift report you go through and list a number of things that you think that Ethicon failed to put into the IFU for the Prolift that they should have put into the Prolift; is that fair to say?
A. Correct.
Q. Is it your opinion that the FDA would have allowed Ethicon to include all of these things in the Prolift IFU or Prolift+M IFU to the extent it is applicable to those devices?
A. I think they would have, because there were some changes that I saw in Ethicon's documents where the FDA came back and said, you need to add this, you need to add this, some of it had to do with the risk of the surgery, and there was some that Ethicon just didn't want to do.
So, yes, I feel like some of the risk verbiage that the FDA wanted in the revised IFU, I think, yes, they would have allowed a lot of what I have suggested.
Q. Are there any limits that you are aware of on what the FDA will allow a medical device manufacturer to include in an IFU?

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A. No, sir, I'm not aware of any limits.
Q. Do you consider yourself to be an expert in FDA regulations?
A. I do not consider myself to be an expert in FDA regulations.
Q. You are not an expert in the FDA regulatory process for bringing medical devices to market, are you?
A. No, I'm not.
Q. What training have you had with respect to the interpretation of FDA regulations, any?
A. No formal training, no.
Q. Any informal training?
A. Just, once again, since all this litigation and concern started, even starting back where the FDA made their first mesh proclamation back a number of years ago, between that and then my involvement in some of the clinical trials I have been involved with, because I was involved with, as you know, TOPAS, and I was also doing some of the 522 studies for AMS.
Q. Is TOPAS an acronym?
A. Yes, sir, transobturator posterior anal sling.

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Q. Through how much of the obturator foramen does the TOPAS point pass?
A. Almost immediately when it traverses the obturator foramen, it dives and goes posteriorly there, so it doesn't really dive into the pelvis like you are thinking like heading into the vagina, it doesn't do that. It immediately, once it passes the bone, it goes south, assuming the patient is sitting on an exam table, it goes posteriorly and then down around the anus and back up.
Q. Does it pass through the obturator internus and externus muscles?
A. Yes, it does.
Q. Have you ever written to the FDA and provided them with your opinion regarding transvaginal mesh kits like the Prolift and Prolift+M?
A. No, I have not.
Q. Have you ever spoken with anyone at the FDA about your opinions regarding the Prolift device or Prolift+M device?
A. No, I have not.
Q. Have you ever had a patient experience a complication following a uterosacral ligament

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suspension that you performed?
A. I'd say an intraoperative complication. I remember over the years having done it, you have to, as we have discussed earlier, you have to really watch out for kinking of the ureters. So I caught that, was able to release the stitch. I don't really remember anything else specific for that.
Q. Do you remember any postoperative complications you have had with a uterosacral ligament suspension?
A. Nothing that stands out, no. I'm not saying I never had it, just nothing stands out in my mind.
Q. Have you ever had a patient experience a postoperative complication following an abdominal sacrocolpopexy?
A. Yes, either from the -- I have opened the abdomen so many times in my career. Certainly I have had some hematomas and some infections of the surgical wound. But I don't remember it -- I'm sorry, I have opened the abdomen so many times, I don't remember specifically.
As far as just something related specifically to the abdominal sacrocolpopexy and not

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just going through the abdominal wall, yes, I have had a vaginal erosion.
Q. Did you report any of those complications to the FDA?
A. No, because I took care of it. It wasn't something that I -- the erosion into the vagina in those cases, none of them resulted in pain with sex or pelvic pain or anything of the sort. The reason we fixed it was because it was just causing a persistent discharge that the patient found annoying.
Q. You are an assistant clinical professor at the Medical College of Georgia; is that right?
A. Yes, sir.
Q. That's here in Athens?
A. It is. There's a branch here now. It was in Augusta, and now there's a branch here in Athens.
Q. Are you one of many professors in that medical college?
A. Probably, yes, sir.
Q. Are there people that have the title of professor, and then people that have different titles like associate clinical professor?
A. Yes, sir.

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Q. As an associate clinical professor, do you teach in a classroom setting?
A. Not yet. The medical school here is relatively in its infancy. I think we just graduated our first four-year class last year. And I have been dealing more with individual medical students on clinical rotations. Most recently, I have had some that rotated with me for their third year rotation, but as of yet, no, I have not taught in a classroom.
Q. The Medical College of Georgia has not sanctioned your activities working as a paid witness on behalf of the Plaintiffs in this litigation, have they?
A. No, they have not.
Q. They haven't endorsed your opinions in any way?
A. No.
Q. You are one employee of many at that medical college?
A. I am not employed, I do it out of the goodness of my heart, I guess.
Q. Do you receive payment from them?
A. No. I think it's just more, I get some

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benefits, like I get to use PubMed and I get to do things of that sort, I get some research, someone can research something for me.

Q. You get to put it on your CV?

A. Right.

Q. Does the Medical College of Georgia know that you are serving as an expert on behalf of the Plaintiffs in this litigation?

A. I don't know. I don't necessarily think so.

Q. Are you an expert in determining corporate motive, knowledge or intent?

A. I would say no.

Q. When did you become an expert on the Prolift+M device?

A. I think -- when I was retained? What's the exact question?

Q. You are testifying here as an expert on the Prolift+M device?

A. Yes, sir.

Q. When did you become that?

A. I feel like in general I'm an expert in mesh and I'm an expert in the surgeries required. I guess, I think I would consider myself more of an

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expert on mesh in general in the pelvis and the use of mesh in general. I haven't really thought about it as I'm an expert just on one particular one with the exception being, of course, I now have in the last several months have learned a lot of very specific things about the Prolift.

I hadn't thought about the question that way.

Q. Have you ever drafted an IFU for a surgical implant for a medical device manufacturer?

A. No.

Q. Have you ever drafted the warning that accompanied an implantable medical device for a medical device manufacturer?

A. No, sir.

Q. Is it fair to say you don't know what processes are followed for preparing medical device warnings?

A. I don't know what the FDA's thoughts are on that matter, no.

Q. Is it fair to say you don't know the regulations governing medical device warnings?

A. I do not know, no.

Q. Have you ever drafted a patient brochure

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for a surgical implantable device?

A. No, sir.

Q. You are not an expert in the design of medical devices, are you?

A. No, sir.

Q. You are not an expert in the design of clinical trials or testing of medical devices, are you?

A. No, sir.

Q. You don't hold yourself out to the community as a warnings expert, do you?

A. No, sir.

Q. Have you had any human factors training or education?

A. What?

Q. Human factors training or education.

A. What is that?

Q. Any training regarding how people interact with warnings and perceive and react to that information, things like that.

A. I would say yes and no. As far as taking a class or something, no. But one of the issues that I was involved with, I think we had to take an online course that dealt with something to that

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effect. So I guess I'm somewhat familiar with that.

Q. You are not a pathologist, correct?

A. Correct.

Q. You are not a materials scientist?

A. Correct.

Q. Have you ever participated in an animal study evaluating polypropylene mesh?

A. No, sir.

Q. Have you ever done any lab or benchtop testing on polypropylene mesh?

A. No, sir.

Q. Have you ever done any biomechanical testing of any polypropylene mesh?

A. I don't know if this would qualify. To me partly it would. As I said, back when I was doing work with Bard, we used to -- we would do cadaver courses and so forth.

I'm not talking about to train other physicians, but where we would look at different meshes or anchorings and we would study pullout strength and that sort of thing. So that might qualify partially, to answer your question.

Q. Do you know what the weight of the Prolift mesh is?

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A. I want to say 28 comes to mind, 28, 29. That's what I think it is.
Q. Do you know what the weight of the Prolift+M mesh is preabsorption of the monocryl component?
A. I do not, off the top of my head.
Q. So you don't know what the weight of the Prolift+M mesh is post the monocryl --
A. Not off the top of my head. I did know it. I can't think of it right now.
Q. Have you carefully reviewed Ethicon's manufacturing documents to understand its premarket testing process for the Prolift of Prolift+M devices?
A. I have reviewed everything that counsel has provided me. I assume you are talking about some of their internal documents and everything as well. I think it's everything that was provided to them.
Q. Do you think that the materials that you have received from the Blasingame law firm is everything that's been provided to them in the pelvic mesh litigation?
A. I think so, from Ethicon. I don't know

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that I have seen every deposition or everything like that that they have taken. I can't comment on that.
Q. When you do a pelvic exam, do you evaluate the ovaries and uterus by transvaginal palpation?
A. Yes, when possible. Sometimes a D&C limits that.
Q. You do that without actually seeing the organs, right?
A. Correct.
Q. Do you perform endometrial biopsies and D&Cs from time to time in your practice?
A. I do.
Q. And do those involve passing an instrument through the cervix into the uterus by palpation?
A. Yes, it does.
Q. You do perform laparoscopic procedures, correct?
A. Yes, sir.
Q. When you do so, do you insert a varus needle through the umbilicus into the abdominal cavity by palpation to insufflate the abdominal cavity?
A. Never.
Q. Do you deliver babies?

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A. Still do.
Q. When you assess a woman's progress in labor by determining cervical dilation, do you do that by palpating the cervix?
A. Digitalization, yes, we do a vaginal exam.
Q. Digital meaning your fingers?
A. We put our fingers in, yes, sir.
Q. Did you review any of Ethicon's design protocols for the Prolift or Prolift+M devices?
A. Design protocols, I reviewed a lot of what they had. I don't know what part of it was a design protocol or not.
Q. How did you decide what materials to cite in the end notes of your report or the footnotes of your reports?
A. As the report was unfolding and I was writing it and revising it and revising it and writing it and revising it, I had all the documents around. And it took a while to do, because I would have to go back and find things.
But basically, I have a locked room at my other office where I keep all the stuff, and that's where I go to write on it. So it's all right there at my fingertips.

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Q. You have a locked room at your office where you keep the stuff that you have produced here today?
A. Yes, sir.
Q. Any other stuff?
A. Any other stuff?
Q. In that locked room regarding your file materials for these cases?
A. Just things that are with this ongoing litigation or whatever. I'm sorry, I don't understand your question.
Q. I want to understand if there are any file materials that you utilized in forming your opinions regarding the Prolift and Prolift+M products that are back in that locked room in your office that aren't here today.
A. Oh, no, no, sir. I'm sorry.
Q. You say at the bottom of Page 21 of your Prolift report that, "Based upon the current literature regarding armed TVM kits and the articles and abstracts regarding the Gynemesh PS and Prolift products, upon what I have observed when I have removed Prolift mesh, and upon what I have learned from my review of Ethicon's internal documents and

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testimony, it is my opinion that the risks of implanting the Prolift far outweighed any perceived benefits with unacceptable rates of mesh exposures, erosions, dyspareunia, urinary and bowel problems, chronic or permanent pelvic pain, painful mesh shrinkage, revisions and reoperations in an attempt to address these complications and recurrences of prolapse following mesh removal surgeries."

Did I read that correctly?

A. Yes, you did.

Q. When you refer to unacceptable rates of those various complications listed there, do you have in mind what an acceptable rate of mesh exposure is?

A. When I was doing my hand-sewn ones, mine was at three percent or less. So for exposure, to have an exposure is not my -- it can be very annoying and concerning to the patient, but if that's the solitary thing, I can fix that. It's these other issues that are a bit concerning.

Q. So a three percent exposure rate is okay with you?

A. That would be ideally even less. My sling exposure rate is less than one.

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Q. When you say sling, what do you mean?

A. Once again, a sling is polypropylene mesh. When we first started out, there were people that were having erosion rates of five to seven percent. Mine for the last several years has been like 0.4 percent there.

Q. Understandably, you want the rate to be as low as possible.

A. Absolutely.

Q. But is a five percent exposure rate acceptable to you?

A. I guess if it delivered as promised and there was none of these other complications, I could probably live with that.

Q. Do you use TVT slings?

A. I don't.

Q. How do you treat stress urinary incontinence?

A. I don't use the TVT brand. I use others slings.

Q. What slings do you use?

A. I use, recently I have used Altus, which is a Coloplast sling. I have used, Desara, I think is it D-E-S-A-R-A, which is by Caldera.

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I have used Sparc, S-P-A-R-C, which is by AMS, but now will be going off the market there.

Q. All polypropylene slings?

A. All polypropylene.

Q. What's an acceptable rate of erosions for you?

A. I would say the same. I'd like it, I mean, erosion and exposure, I'm sorry, in my mind I kind of lump them in because they are in the vagina.

Q. Five percent would be okay?

A. Or less, yes, as low as possible.

Q. What's an acceptable dyspareunia rate for you in a pelvic organ prolapse repair?

A. Zero.

Q. One percent is unacceptable?

A. No, I guess I could live with that. Obviously, it is probably the thing that one patient, if they have severe dyspareunia and previously their sex life was good, it is a horrible thing to take care of.

Q. The next page, Page 22, you talk about how there were alternative designs available for the Prolift kits, right? We have talked a bit about that today already?

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A. Yes, sir.

Q. One thing you say there is "introduction of stress shielding to prevent pore collapse."

What do you mean by that?

A. What stress shielding is referring to in this sentence there is that material that you put in, it takes the physical forces or the stress off the surrounding tissues. You certainly have to be careful with the terminology because, and in the long term, you don't want stress shielding to necessarily be there, because if you remember the Moalli study we discussed, it was felt that some of the vaginal degeneration that was seen with the Prolift mesh was due in fact to stress shielding.

Now, in my mind, I may have this wrong, but in my mind, stress shielding, the way I meant the connotation here is, you want it there in a way to protect the pore size to keep the mesh lying flat, to keep the mesh pores open such that ingrowth can occur. Once that occurs, the stress shielding ideally could wither away or go away.

Q. Does abdominally placed polypropylene mesh degrade, in your opinion?

A. Yes.

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Q. Do you believe that Proline sutures degrade?
A. Yes.
Q. On Page 22 at the bottom of the page you say, "I personally observed and treated patients who have been implanted with Ethicon Prolift products that experienced the following device-related complications." And then on the next page you say that, "Those are directly attributable to the defective design of these products as described previously."
Right?
A. Yes.
Q. What design defect in the Prolift and Prolift+M devices causes chronic or permanent pelvic pain?
A. That had to do with the armed nature of the mesh which we have discussed as well as the chronic and ongoing inflammatory/foreign body response induced by the degrading polypropylene mesh.
Q. Anything else?
A. I think that the other thing is poor surgeon training.

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Q. Have you ever developed a training course for surgeons to go through in preparation for using a medical device for the first time?
A. No. I've taught some very small ones and I was given kind of free reign to do what I wanted, but no, I don't think I built it from the ground up.
Q. What design defect causes chronic or permanent inflammation of tissues surrounding mesh?
A. That's going to be the degradation of the polypropylene.
Q. Anything else?
A. That's the main thing.
Q. What defect in the Prolift or Prolift+M devices causes excessive scar plate formation, scar banding and contracture of mesh arms? I will leave it at that.
A. Sir?
Q. I'll leave it at that.
A. One, that's going to be your adequate or inadequate pore size once the mesh is placed. You want the mesh to maintain its pore size until the ingrowth occurs.
That is where you are going to get your bridging, your bridging fibrosis which is going to

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lead to your scar banding. When you are talking about the arms, then that has to do with the curvature of the arms and basically the mesh arms end up by curving and overlapping themselves. That doubles your mesh density which is going to cause excessive scar plate formation.
Q. What defect in the Prolift or Prolift+M devices causes erosion of mesh into the bladder and rectum and exposure of mesh into the vagina?
A. Once again, obviously, you can't say something like that without commenting on surgical training and surgical technique. But then once again, in something like that where you basically have created like a fistula-type track, inflammation and chronic inflammation is a key point.
Q. What defect in the Prolift and Prolift+M devices, design defect, that is, causes pudendal neuralgia?
A. That can be many things. Number one, it can be the technique itself of passing these trocars blindly. I believe it was the posterior pass that advocated going through the sacrospinous ligament where traumatically the pudendal nerve would be the most at risk of being ensnared in the resultant mesh

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arm or lacerated by the tip of the trocar.
Additionally, it has been well-described in the literature the fibrosis around such, how it can affect the surrounding nerves. And nerves can end up getting entrapped or encapsulated in the ongoing fibrotic response.
So it can be the actual technique itself, whether it's from a poor design by a manufacturer or the execution of that by the surgeon. But also, once again, the chronic inflammation is going to play a role in this.
Q. What is the generally accepted method for measuring pore size or porosity in mesh?
A. I believe, if I'm not mistaken, that is with a SEM scan, scanning electron microscopy, I believe. I don't think it is TDM, I think it is scanning electron microscopy.
Q. Can you hold a ruler up to the mesh to measure the pore size?
A. Wait a minute, we are talking about the macro picture, the mesh is laying there, that type of thing.
Q. Yes.
A. Yes, you can do that. I forgot what

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amount of force if any is put on it, but yes, you can do that. I was thinking about microscopically.

Q. Have you ever taken a piece of Gynemesh PS or ULTRAPRO mesh and laid it next to a ruler and measured how big the pores are?

A. No.

Q. What's the design defect in the Prolift or Prolift+M devices that in your opinion causes pelvic floor muscle spasms?

A. Once again, the chronic inflammation; the passage of these arms through the various muscles that are present; as well as the irritation and inflammation of the nerves. Once these nerves -- this has been well-described -- are chronically irritated, their threshold for wanting to fire is actually lowered dramatically.

So then things that might otherwise stimulate a pelvic floor muscle contraction -- excuse me, things that otherwise would not stimulate a pelvic floor muscle spasm are now stimulating them. It may just be activities of daily life.

Q. How much farther away does the TOPAS sling traverse from the pudendal nerve than the Prolift?

A. Gosh, it is like the equivalent from here

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to California. It is not even in the ballpark.

Q. How many centimeters?

A. Gosh, six, seven, eight, nine.

Q. What's that based on?

A. Just knowledge of anatomy. It's nowhere close.

Q. Is there a cadaver study that's been done that shows that difference?

A. I think if I can show you on a skeleton, you would see it is not even in the same neighborhood.

Q. What is the design defect in the Prolift or Prolift+M devices that causes nerve damage and dyspareunia?

A. Once again, that is, the nerve damage can be many ways. One, it can be the passage -- once again, I guess now we are not talking about pudendal nerve anymore, we are talking about nerves in general here, just to be clear.

So nerve damage as you get excessive fibrosis or scarification, numerous pathology studies have shown that they found nerve fibers in this. So the nerves can get caught up in this ongoing severe scarification is going to be a result

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of the healing as well as the chronic ongoing inflammation. Scarification, once again, obviously we said earlier in this deposition, is a good thing for healing, but at some point it needs to quit.

Q. Is there a standardized weight classification system for mesh?

A. Standardized weight, like if it is 20 micrograms, it is low weight; if it is 30 micrograms it is --

Q. Right.

A. I don't know that it is standardized.

Q. So there is no standardized weight classification system that you know of for mesh?

A. Not right off. I think it is one of those things, you kind of know it when you see it.

Q. Do you agree that with any implant in any part of the body, there's the possibility of a chronic foreign body reaction?

A. I think that's a very fair statement.

Q. Not every chronic foreign body reaction leads to pain; is that fair?

A. That's correct.

Q. Recurrence of prolapse is a possibility with any pelvic organ prolapse procedure, correct?

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A. Yes, sir.

Q. Just because recurrence of prolapse is possible with a pelvic organ prolapse procedure doesn't mean that procedure or device is defective, does it?

A. Yes and no. So, for example, if the prolapse recurred because of a problem with the device that you had to go in and required its removal, I attribute that to the device.

Q. What is the alleged design defect with the Prolift or Prolift+M devices that you think causes stress urinary incontinence, urge incontinence or urinary retention?

A. I think you have to break those down carefully. Urinary retention is probably going to be twofold. One is going to be perhaps related to the dissection or improper dissection required, even though I will say I found it interesting that there was an email in Ethicon's stuff from David Robinson regarding a couple of patients that he was made aware of that had urinary retention, and both of these patients were operated on by what I intimated to be KOLs. One of them was Dennis Miller there.

It seemed to be prolonged and ongoing and

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and ongoing and ongoing after several weeks. So it raises a question of, is that related to the actual passage of the arms and digging up some of the nerves and so forth.

As far as the stress urinary incontinence goes, I think some of that has to do with, once again, with the training there. The urge incontinence is going to be more related to the chronic irritation and inflammation going on and lowering the threshold for the nerves to fire.

Q. I added up on your invoices that we have marked as Exhibit 6 the total amounts reflected on those invoices. That amount was $90,375. Does that sound about right in terms of the amount you have been paid or have invoiced for your work in the pelvic mesh litigation involving Ethicon?

A. It sounds about right, yes, sir.

Q. How much have you earned to date from your work as an expert witness in all of the transvaginal mesh litigation combined, not just limiting it to Ethicon?

A. $250,000. I don't know. With this 90,000 that you just mentioned and what I have done before, it's probably at least 250.

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Q. You earn $4,000 for a half day of trial testimony and $8,000 for a full day?

A. Yes, sir.

Q. For your deposition time, you earn $600 per hour with a minimum four-hour charge?

A. Yes, sir.

Q. For travel time to the deposition, you earn $200 in 30-minute increments?

A. Yes, sir.

Q. So if it goes 36 minutes, you would charge $400 for that hour of travel?

A. Yes, sir. I think the first hour I probably would do just 200 and after that -- I'm sorry, I'm getting confused now.

Q. When you travel to testify at a trial for Mr. Hill's firm, the Blasingame firm, how do you get there?

A. I have flown.

Q. Did you fly commercial or on a private plane or jet?

A. It's private.

Q. Did you ever fly in a commercial plane or jet to get to a trial involving the Blasingame firm?

A. No, sir.

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Q. Is it a private jet or a private plane?

A. One was a private plane I think owned by somebody in the firm. The other was a jet.

Q. Have any medical device manufacturers flown you anywhere on a private jet or plane?

A. No, sir.

Q. Are you billing for your travel time when you are on the private plane or private jet?

A. I am, at the rate I mentioned.

Q. Who created the reliance lists that we have marked as Exhibits 11 and 12?

A. I think I gave kind of a hodgepodge list which the secretaries here kind of collated for me, if that makes sense.

Q. The way it was produced to us, there was a 29-page list and a 131-page list. Does that sound about right?

A. Yes, sir. There was a lot of documentation that I reviewed at one time or another.

Q. What's the difference between those two lists, if you know?

A. The difference, you mean as far as the specific articles or whatnot?

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Q. Why were there two separate lists prepared in that regard?

A. Well, is one not for Prolift and Prolift+M?

Q. No, the way it was produced to us, there is a 29-page reliance list for Prolift in addition to a 131-page list for the Prolift, and then there's the same thing for the Prolift+M.

A. I'm sorry, I misunderstood what you were asking. I don't know why we broke it up into two separate ones. I'm sorry, I didn't understand.

Q. Between what's included in your reports and with we have discussed today, have we discussed all of your opinions regarding the Prolift and Prolift+M devices?

A. I think we have. We have covered a lot of what was in my IFUs, I think.

Q. Thank you.

(Deposition concluded at 2:19 p.m.)

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ACKNOWLEDGMENT OF DEPONENT

I,_____, do hereby certify that I have read the foregoing pages, and that the same is a correct transcription of the answers given by me to the questions therein propounded, except for the corrections or changes in form or substance, if any, noted in the attached Errata Sheet.

_____

ROBERT BRIAN RAYBON, M.D. DATE

Subscribed and sworn to before me this _____ day of _____, 20____.

My commission expires:_____

_____

Notary Public

CERTIFICATE

GEORGIA:

HENRY COUNTY:

I hereby certify that the foregoing deposition was reported, as stated in the caption, and the questions and answers thereto were reduced to the written page under my direction; that the foregoing pages 1 through 245 represent a true and correct transcript of the evidence given. I further certify that I am not in any way financially interested in the result of said case.

Pursuant to Rules and Regulations of the Board of Court Reporting of the Judicial Council of Georgia, I make the following disclosure:

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This, the 20th day of April, 2016.

_____

MAXYNE BURSKY, CCR-2547